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Raymond et al.

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(54) **DEVICES AND METHODS FOR INSERTING A SPINAL FIXATION ELEMENT**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 177 days.

(21) Appl. No.: **11/051,983**

(22) Filed: **Feb. 3, 2005**

(65) **Prior Publication Data**

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Related U.S. Application Data

(60) Provisional application No. 60/542,548, filed on Feb. 6, 2004, provisional application No. 60/565,784, filed on Apr. 27, 2004.

(51) **Int. Cl.**
A61B 17/88 (2006.01)

(52) **U.S. Cl.** **606/279**; 606/99

(58) **Field of Classification Search** .... 606/60-61, 606/99, 246, 250-262, 264-279, 96, 104, 606/323, 198, 914, 916, 86 A
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,913,134	A	4/1990	Lugue
5,242,446	A	9/1993	Steffee
5,984,923	A	11/1999	Breard
6,235,028	B1	5/2001	Brumfield
6,458,491	B1	10/2002	Wimberly
6,530,929	B1	3/2003	Justis
6,540,749	B2	4/2003	Schafer
6,554,831	B1	4/2003	Rivard
6,652,527	B2	11/2003	Zucherman
7,008,422	B2	3/2006	Foley
2002/0116000	A1	8/2002	Zucherman

(Continued)

FOREIGN PATENT DOCUMENTS

DE	3434807	12/1985

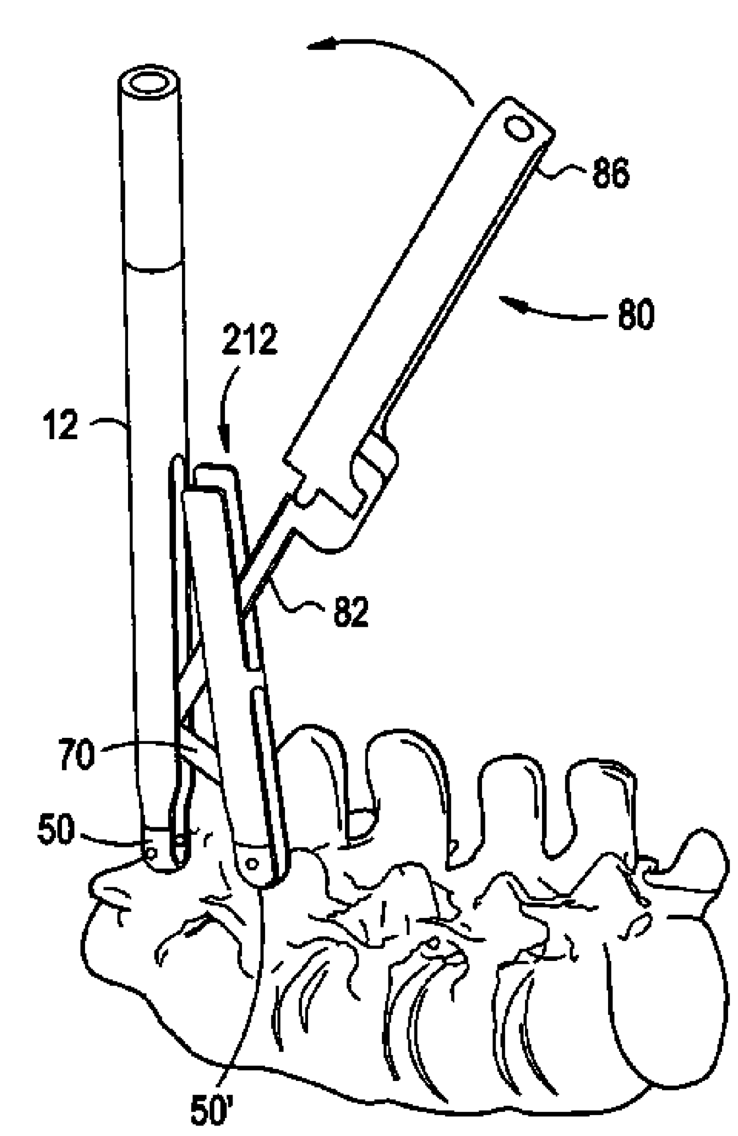
(Continued)

Primary Examiner—Eduardo C Robert
Assistant Examiner—James L Swiger, III

(57) **ABSTRACT**

A method for introducing a spinal fixation element between two bone anchors includes engaging a spinal fixation element to a shaft of an instrument, positioning the shaft of the instrument through a sidewall opening of a first percutaneous access device connected to a first bone anchor and through a side wall opening of a second percutaneous access device connected to a second bone anchor, the spinal fixation element extending in an orientation substantially parallel to the longitudinal axis of at least one of the first percutaneous access device and the second percutaneous access device, and pivoting the instrument to change the orientation of the spinal fixation element and position the spinal fixation element in proximity to the first bone anchor and in proximity to the second bone anchor.

12 Claims, 58 Drawing Sheets



U.S. PATENT DOCUMENTS

2002/0138077	A1	9/2002	Ferree
2002/0169448	A1	11/2002	Vanacker
2003/0083657	A1	5/2003	Drewry
2003/0208203	A1	11/2003	Lim
2003/0229347	A1	12/2003	Sherman
2004/0138662	A1	7/2004	Landry
2004/0143265	A1	7/2004	Landry
2005/0065516	A1	3/2005	Jahng
2005/0085813	A1	4/2005	Spitler
2005/0090824	A1	4/2005	Schluzas
2005/0131408	A1	6/2005	Sicvol
2005/0131419	A1	6/2005	McCord
2005/0131420	A1	6/2005	Techiera
2005/0131421	A1 *	6/2005	Anderson et al. 606/99
2005/0131422	A1	6/2005	Anderson
2005/0192570	A1	9/2005	Jackson
2005/0192579	A1	9/2005	Jackson
2006/0030839	A1	2/2006	Park
2006/0036244	A1	2/2006	Spitler
2006/0036255	A1	2/2006	Pond
2006/0074445	A1	4/2006	Gerber
2006/0079894	A1	4/2006	Colleran
2006/0084993	A1	4/2006	Landry
2006/0095035	A1	5/2006	Jones
2006/0106380	A1	5/2006	Colleran
2006/0111712	A1	5/2006	Jackson
2006/0111713	A1	5/2006	Jackson
2006/0111714	A1	5/2006	Foley
2006/0122597	A1	6/2006	Jones
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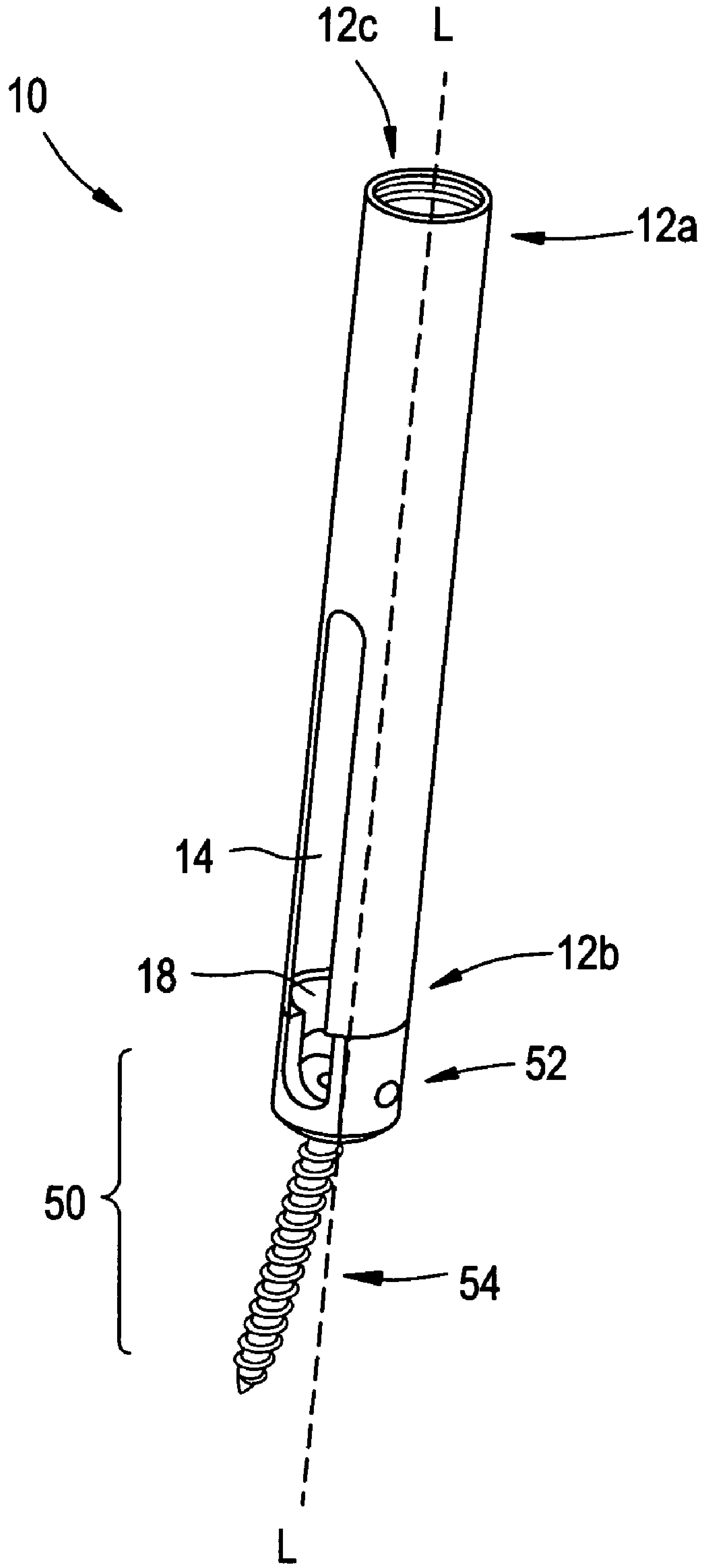
FOREIGN PATENT DOCUMENTS

WO	0128436	4/2001
WO	2004041100	5/2004

* cited by examiner

FIG. 1



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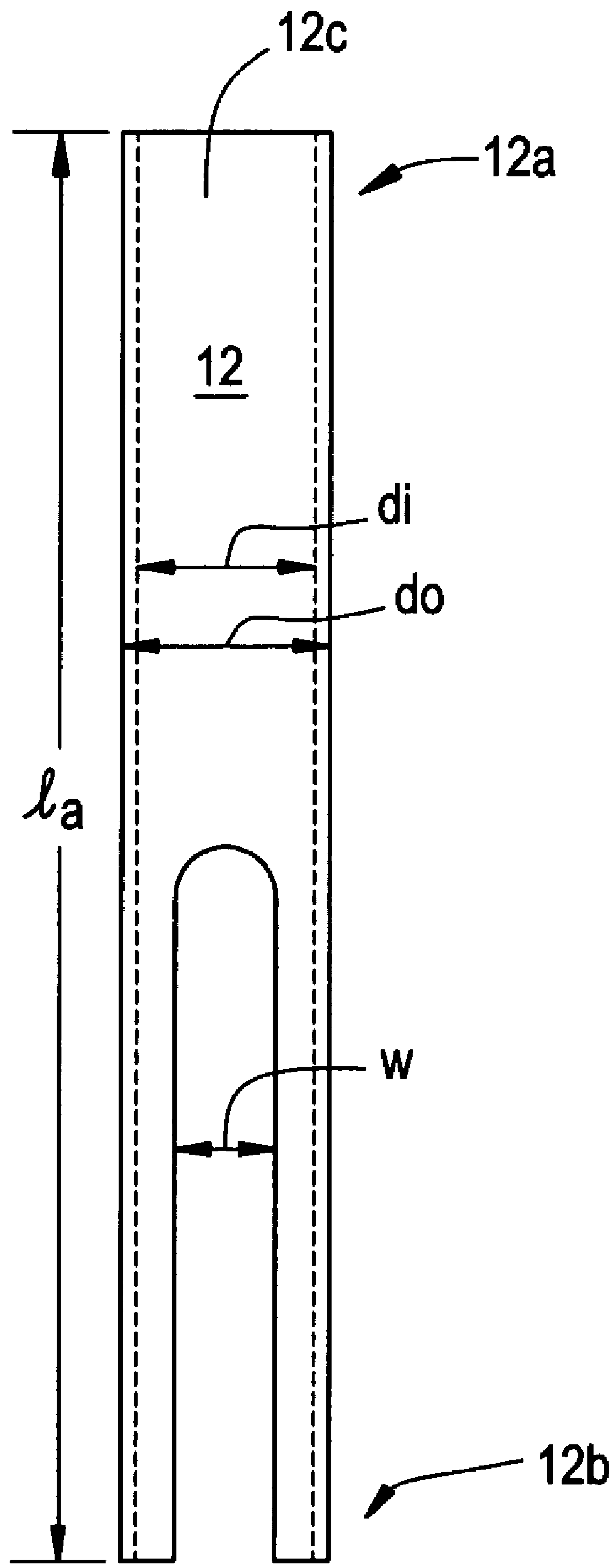

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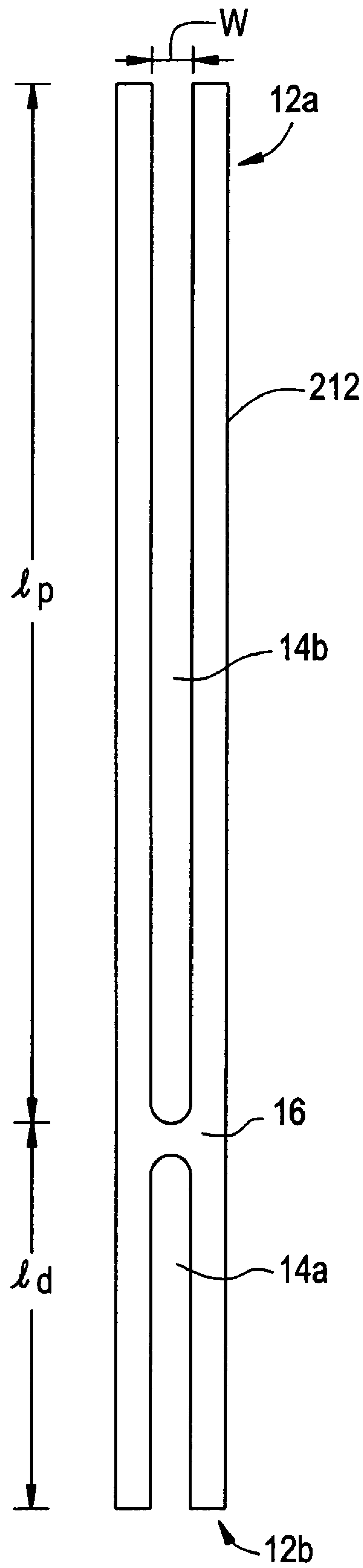

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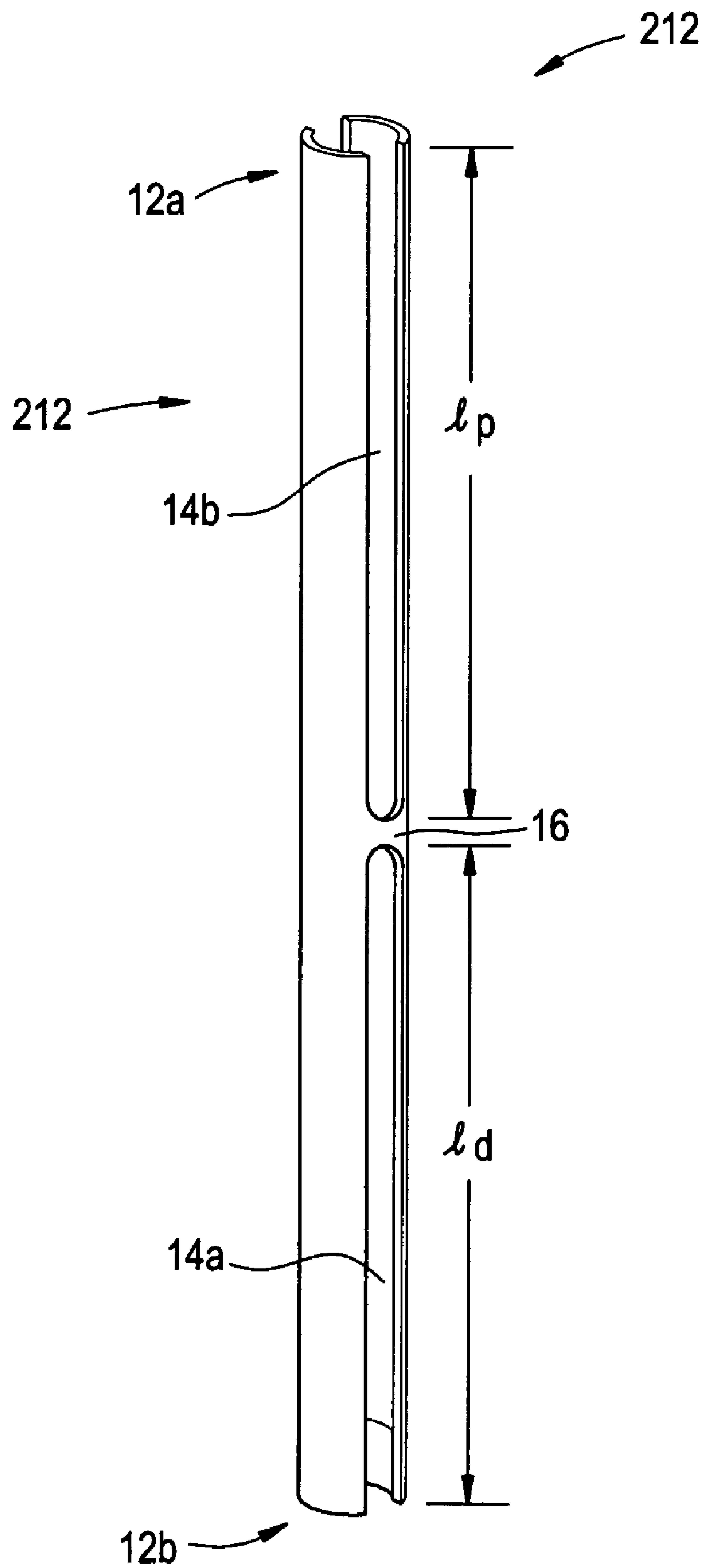

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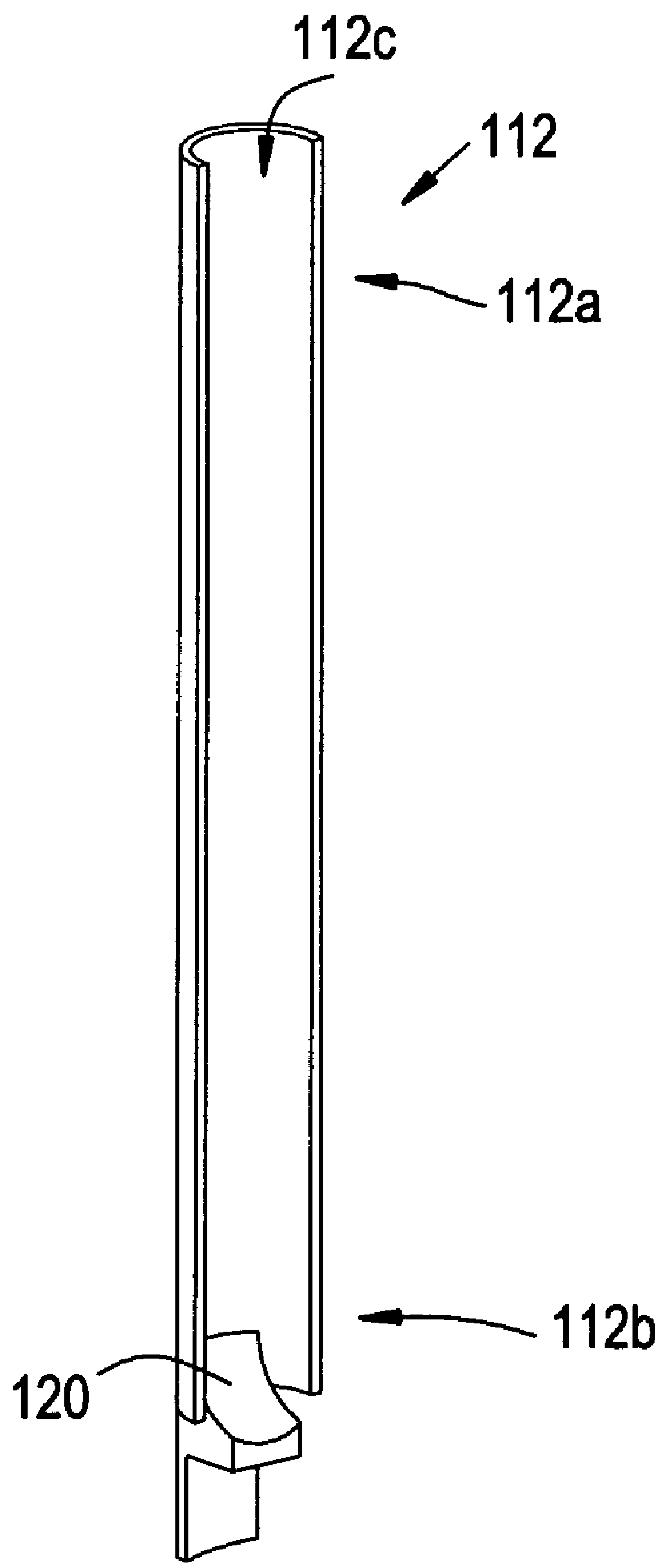
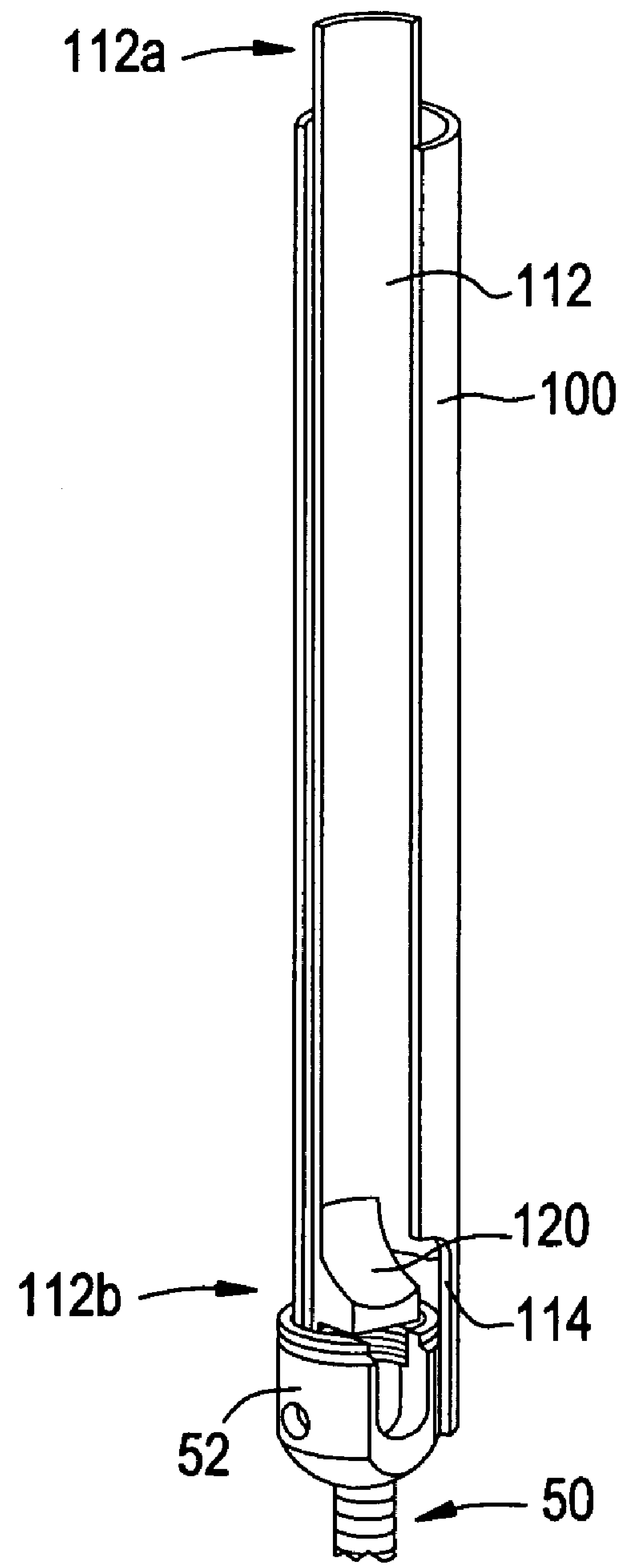


FIG. 5B



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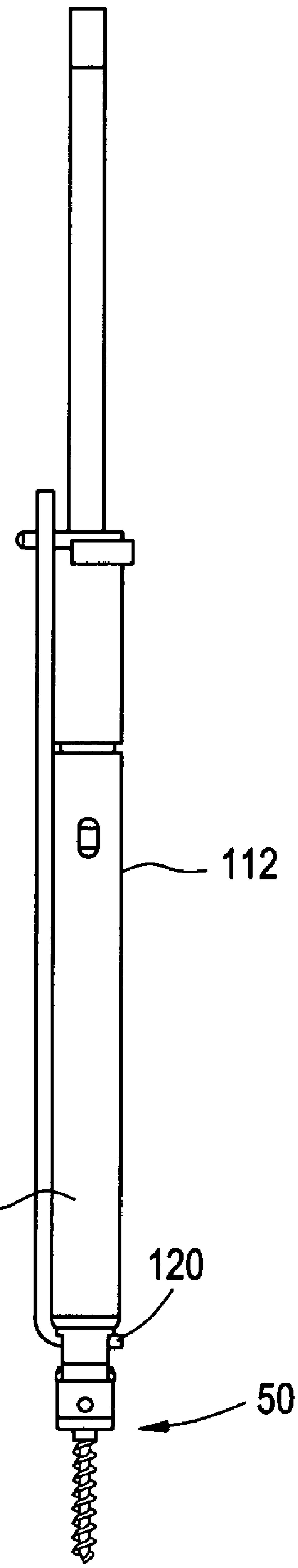

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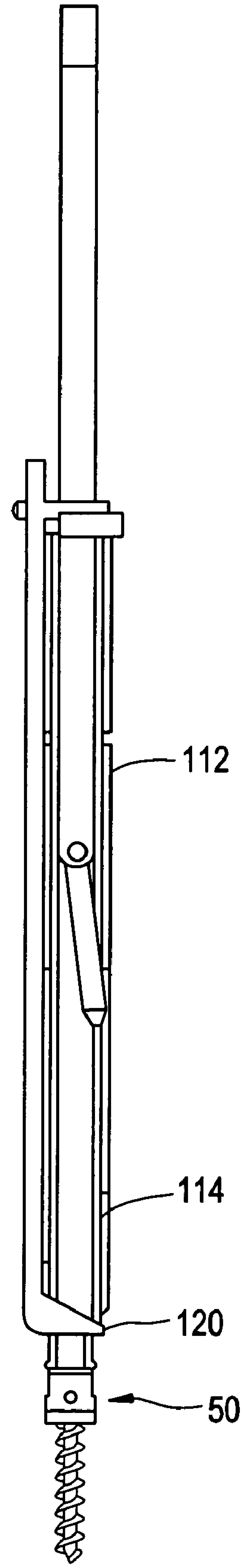

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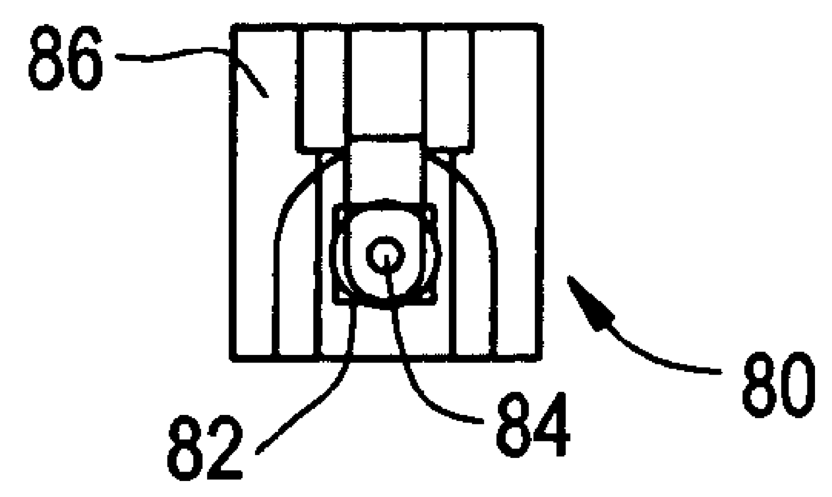

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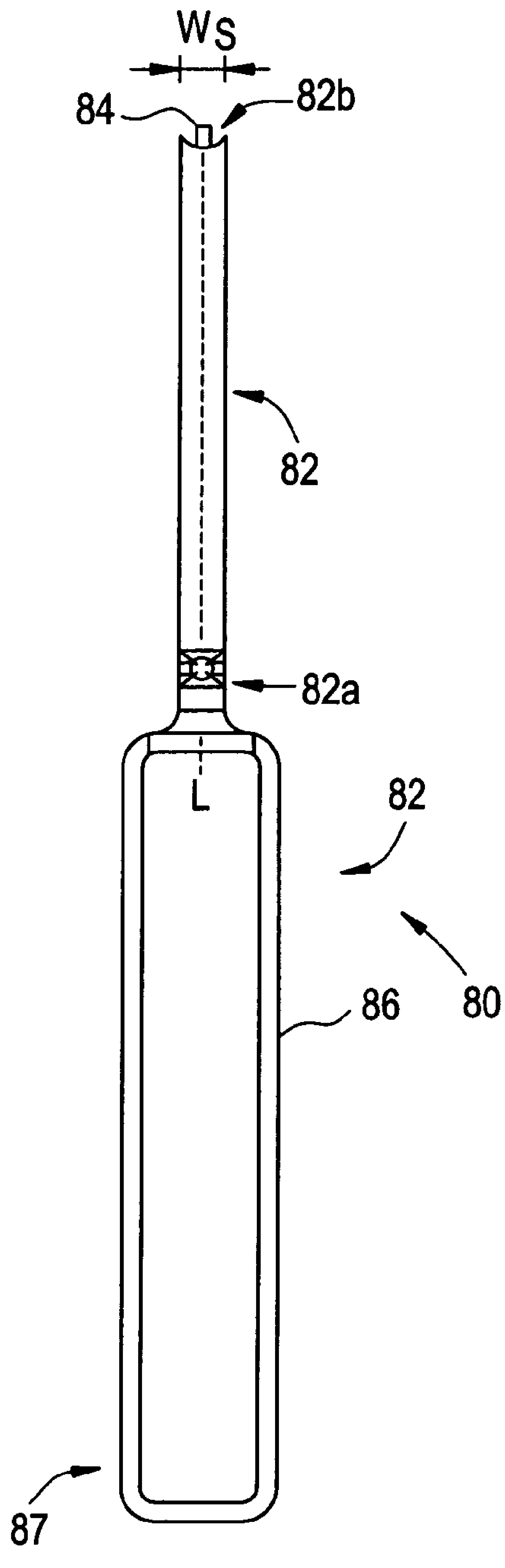

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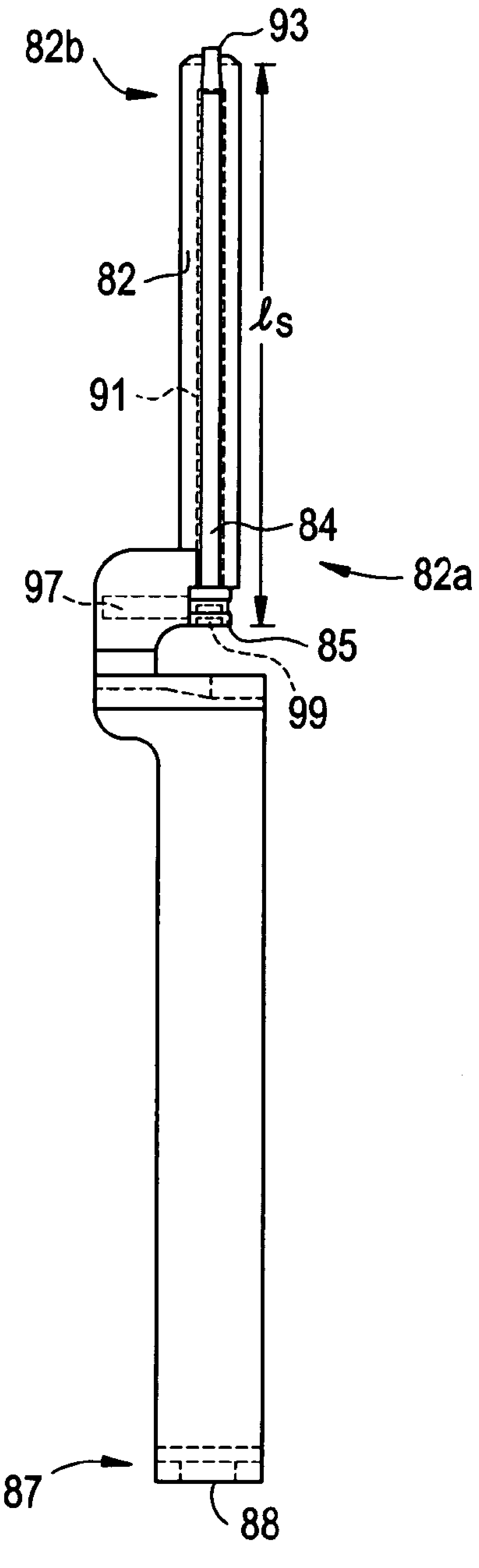

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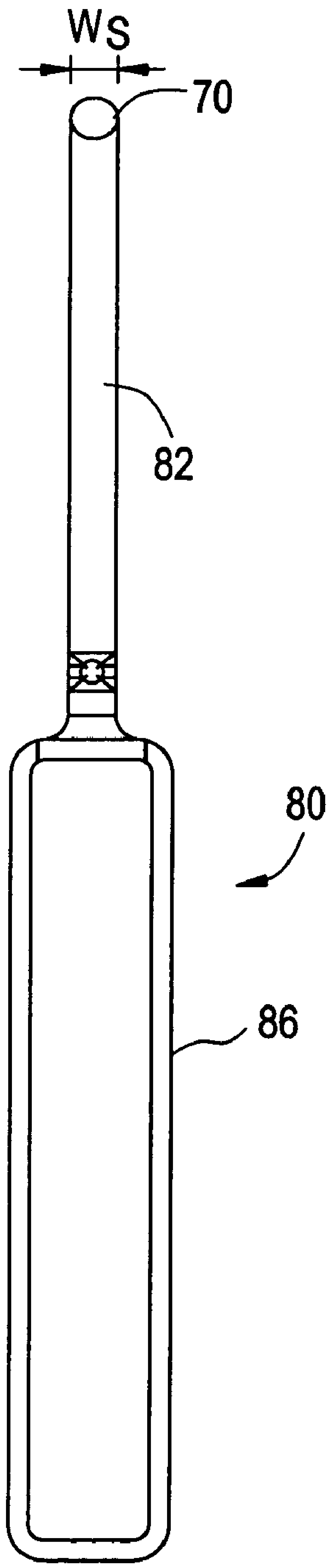

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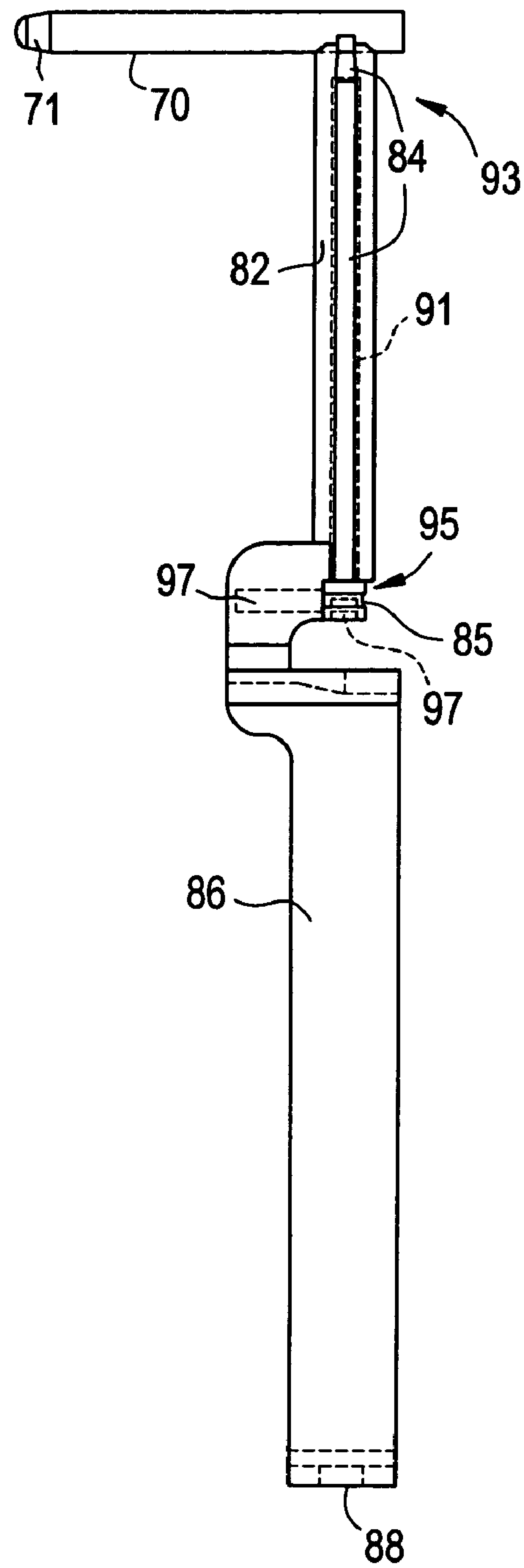

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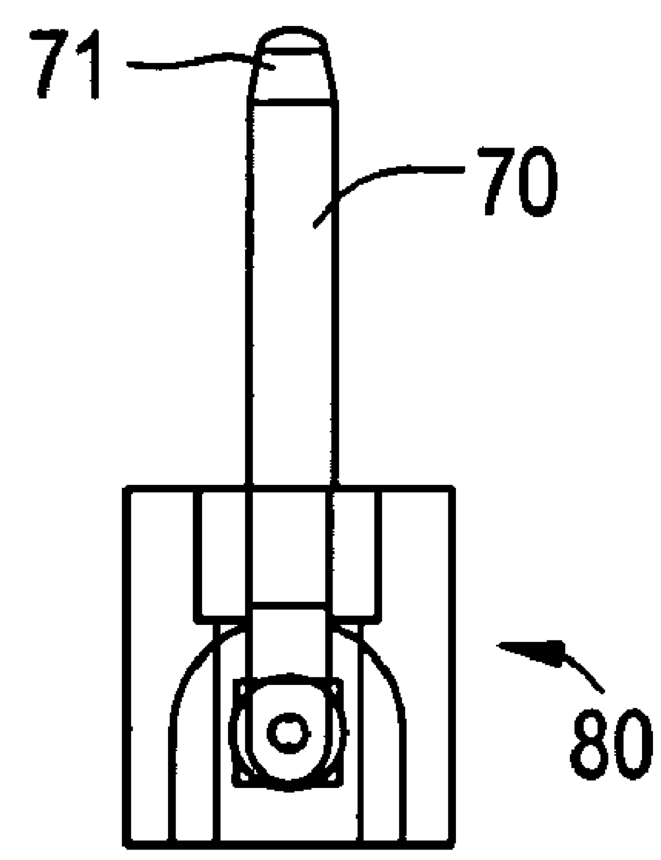


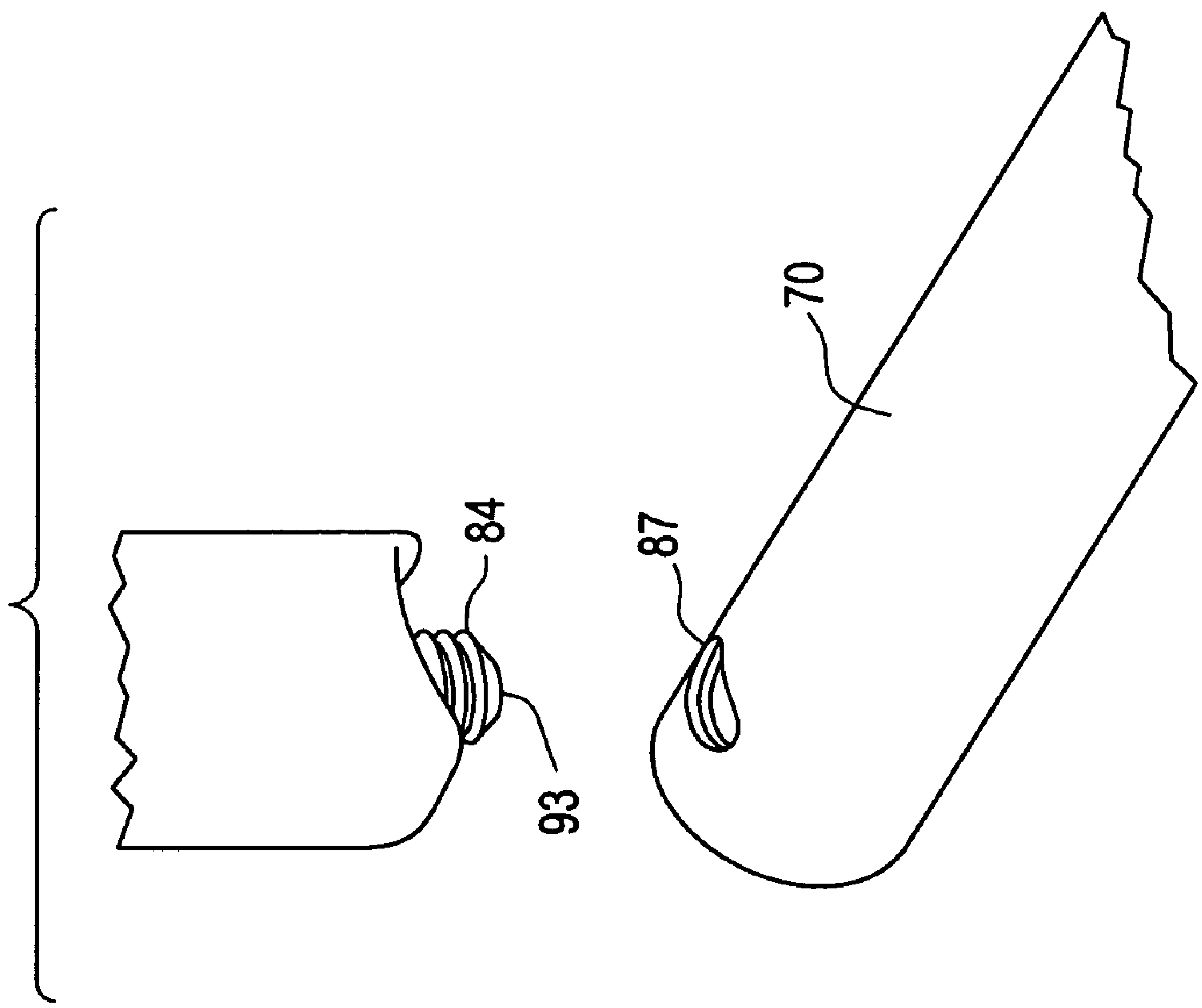
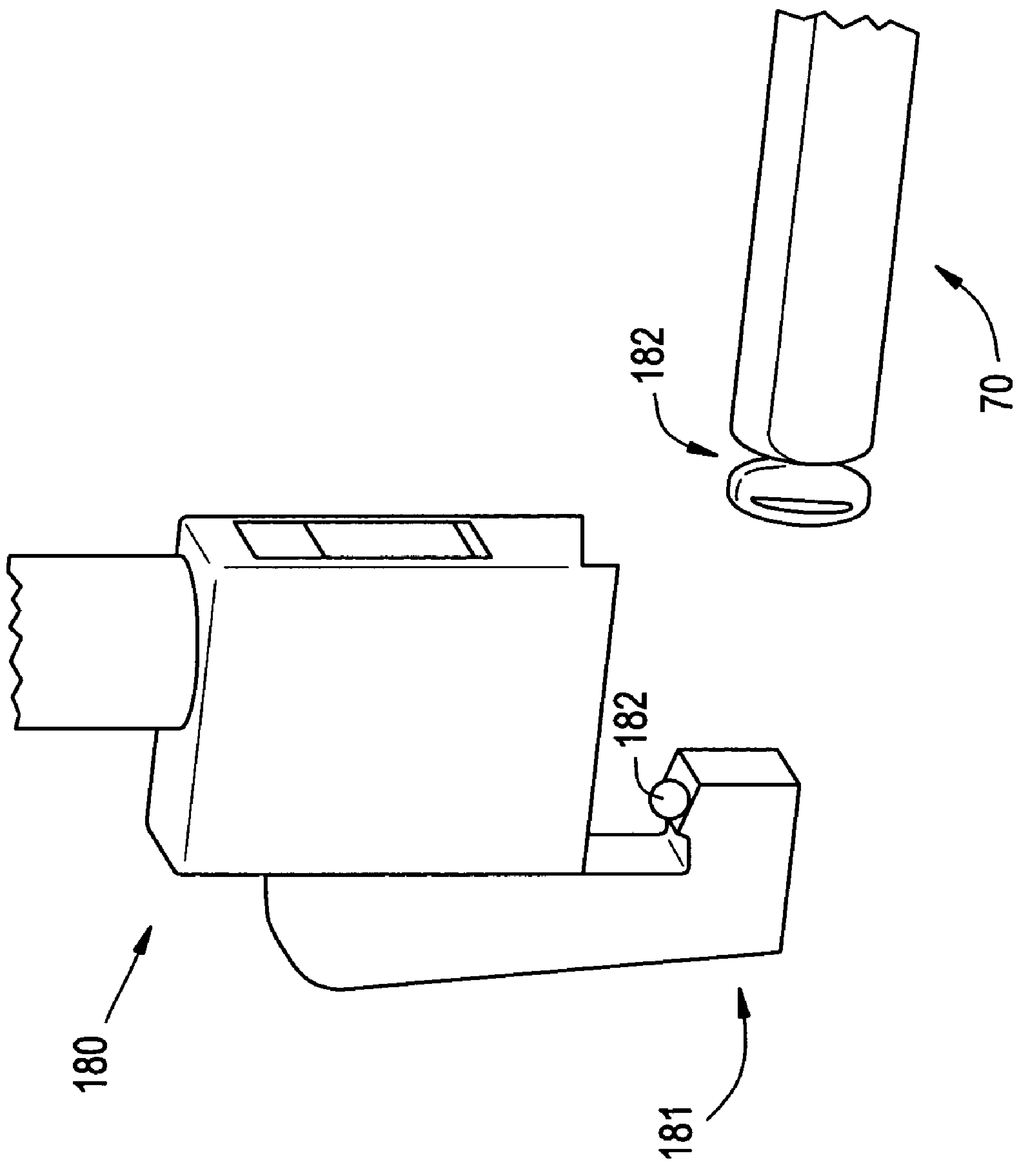
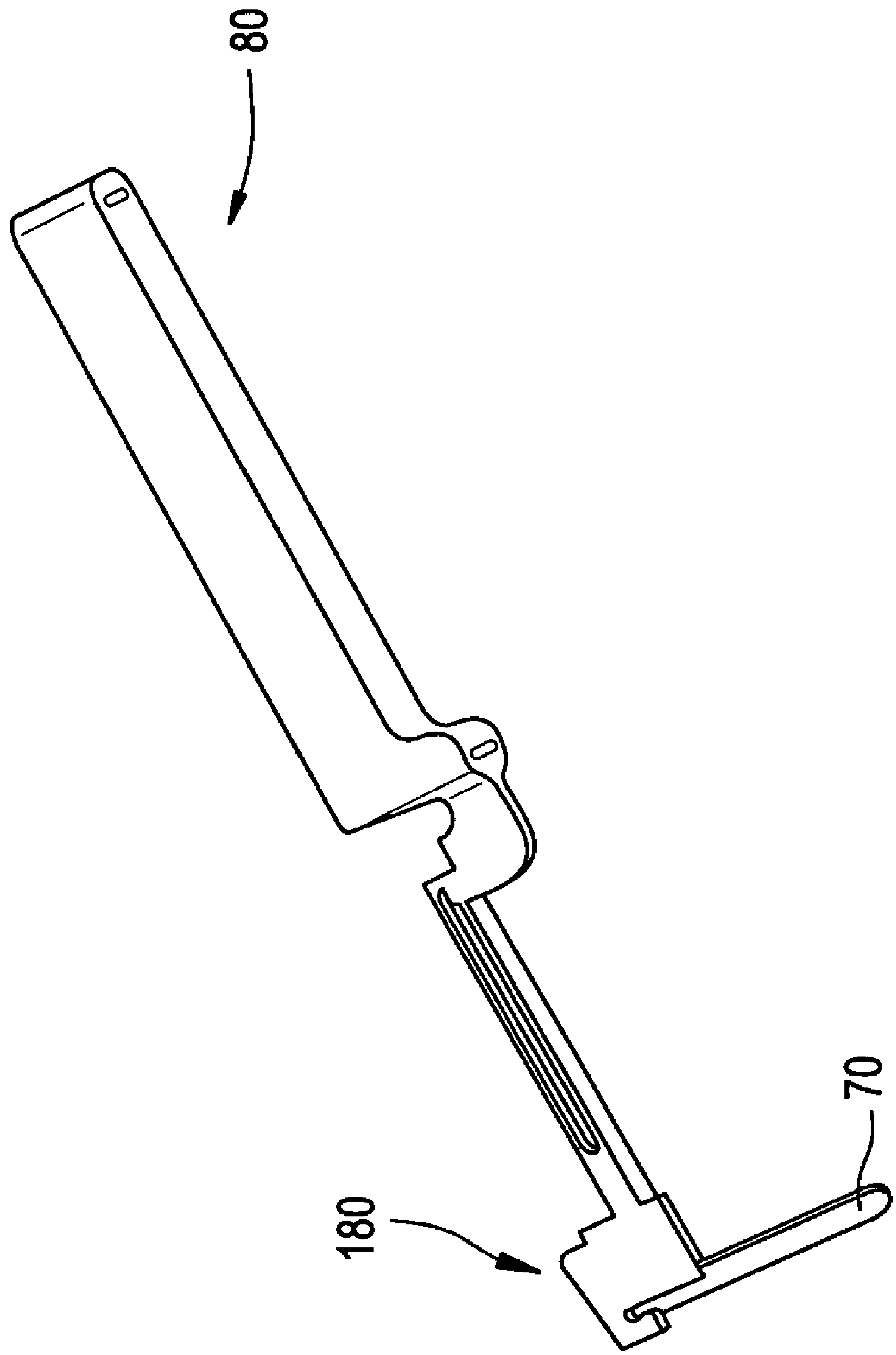


FIG. 8D

FIG. 9A





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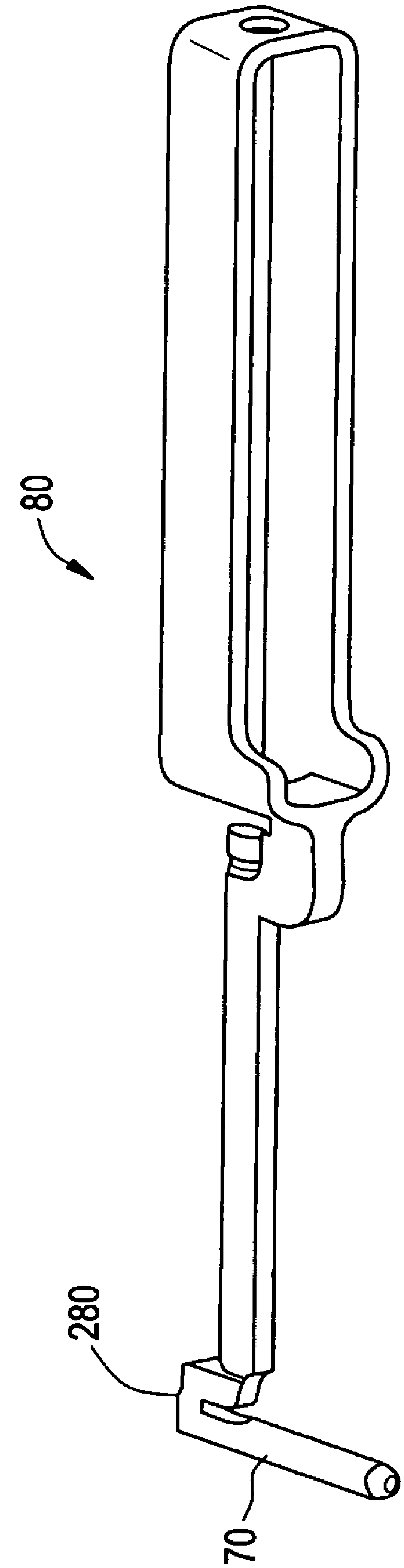

FIG. 10A

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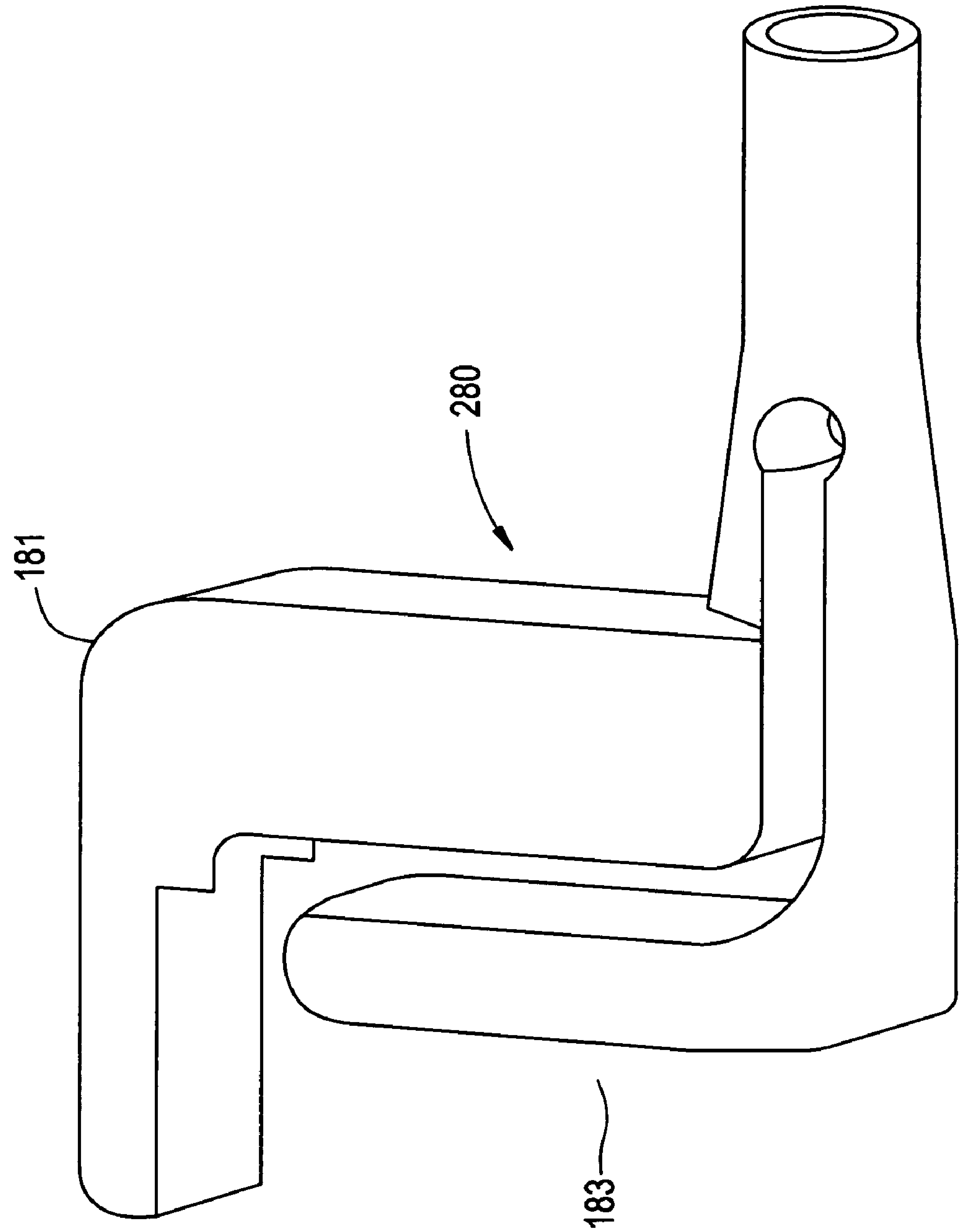

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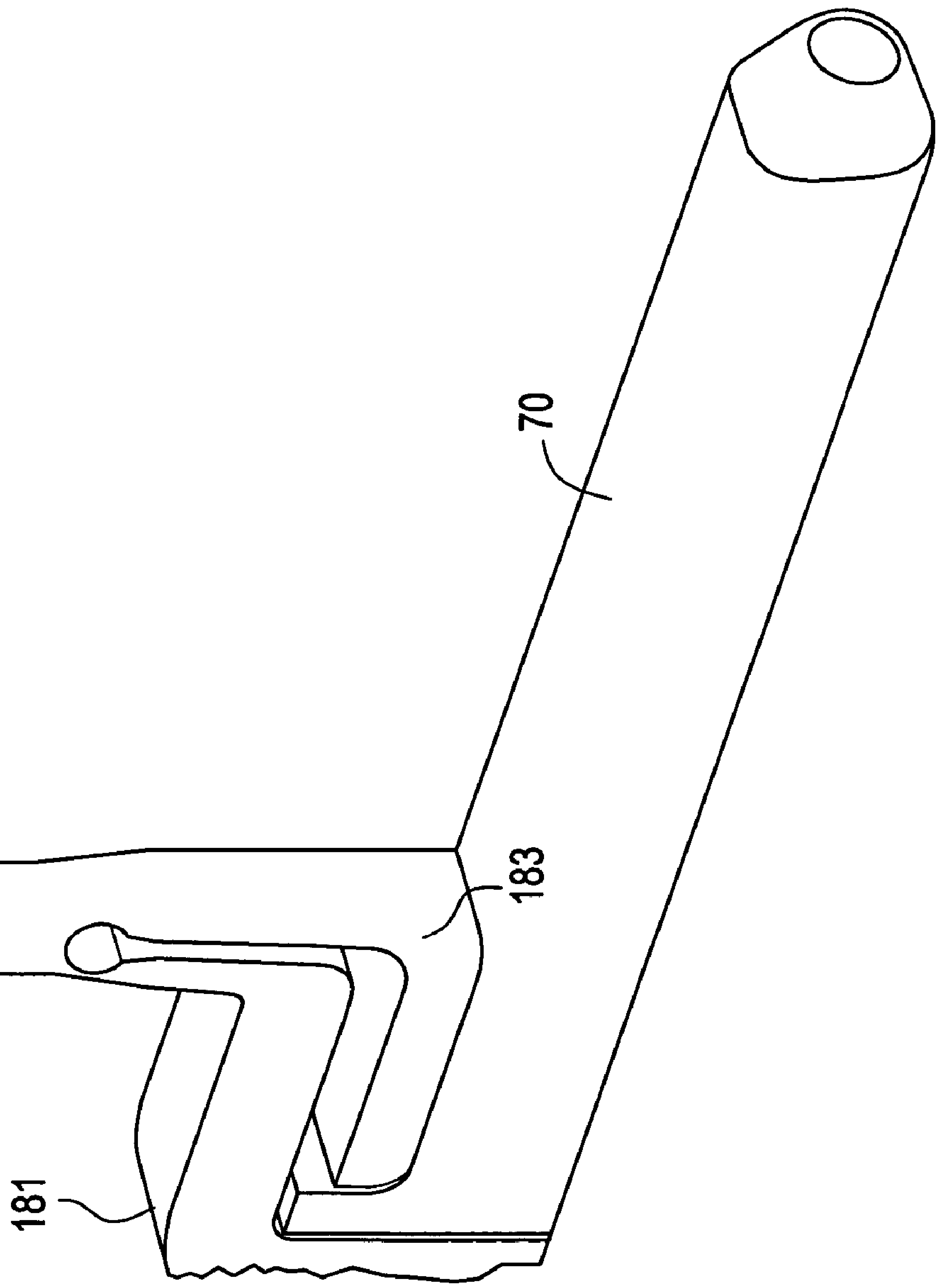

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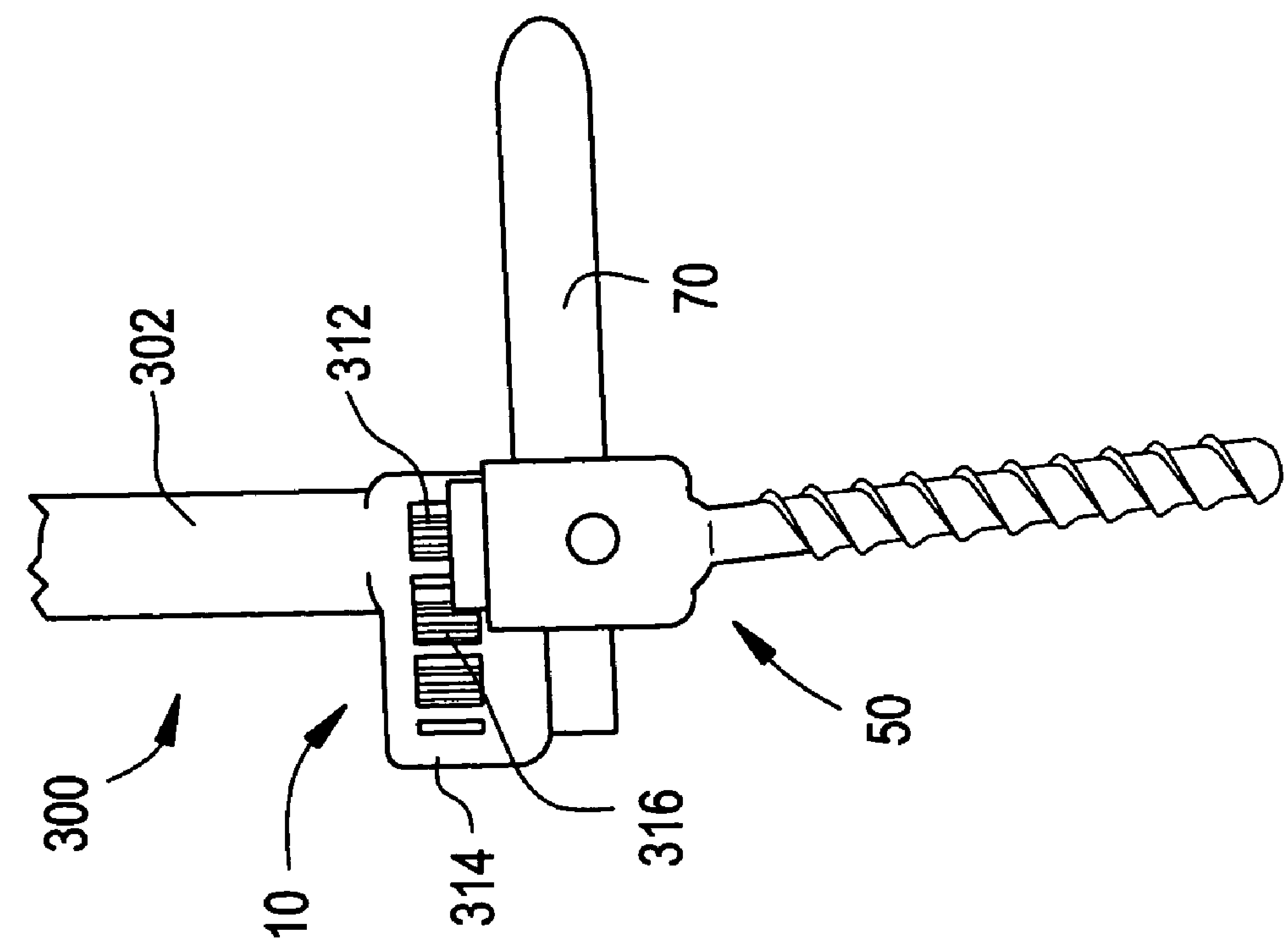

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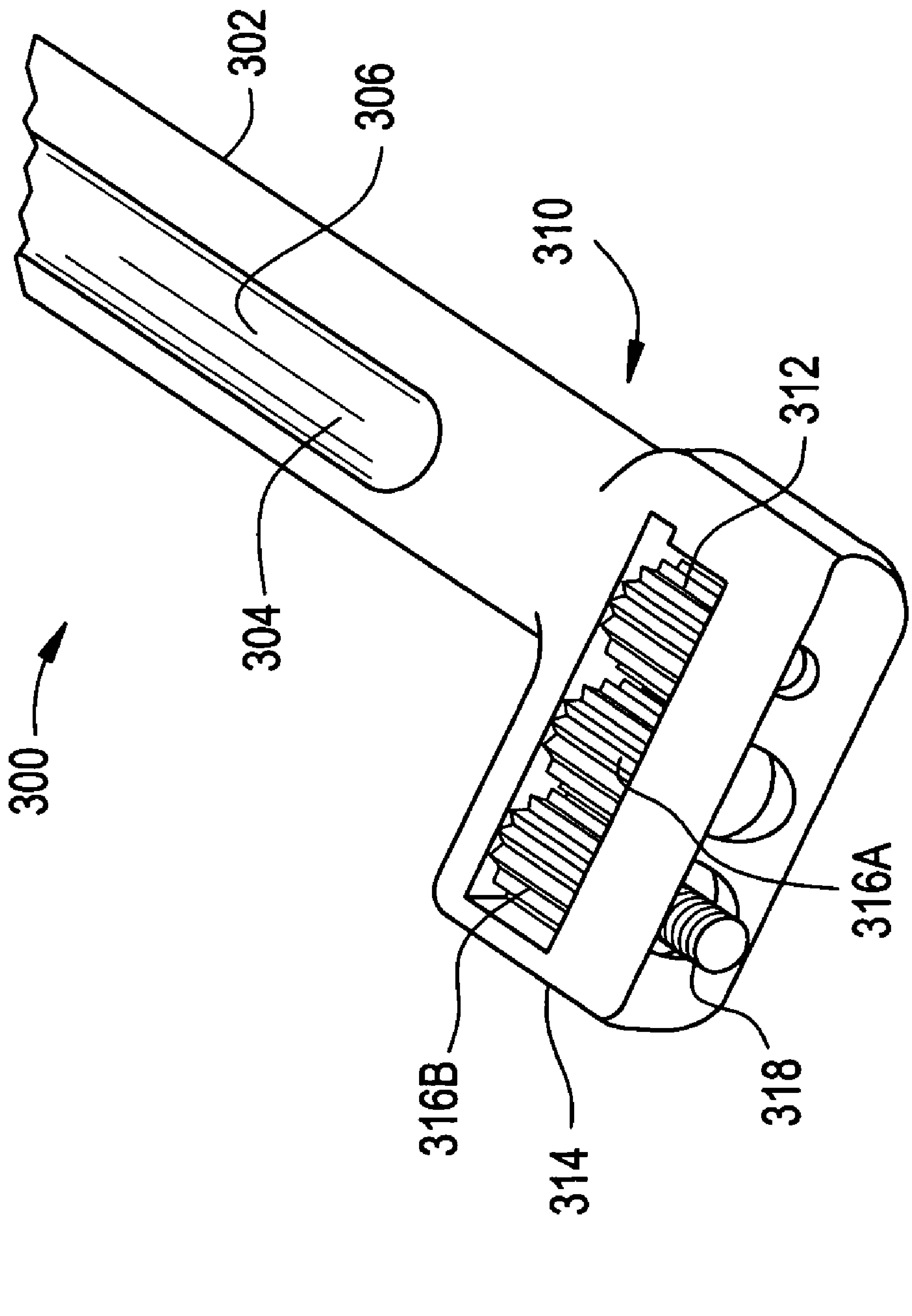

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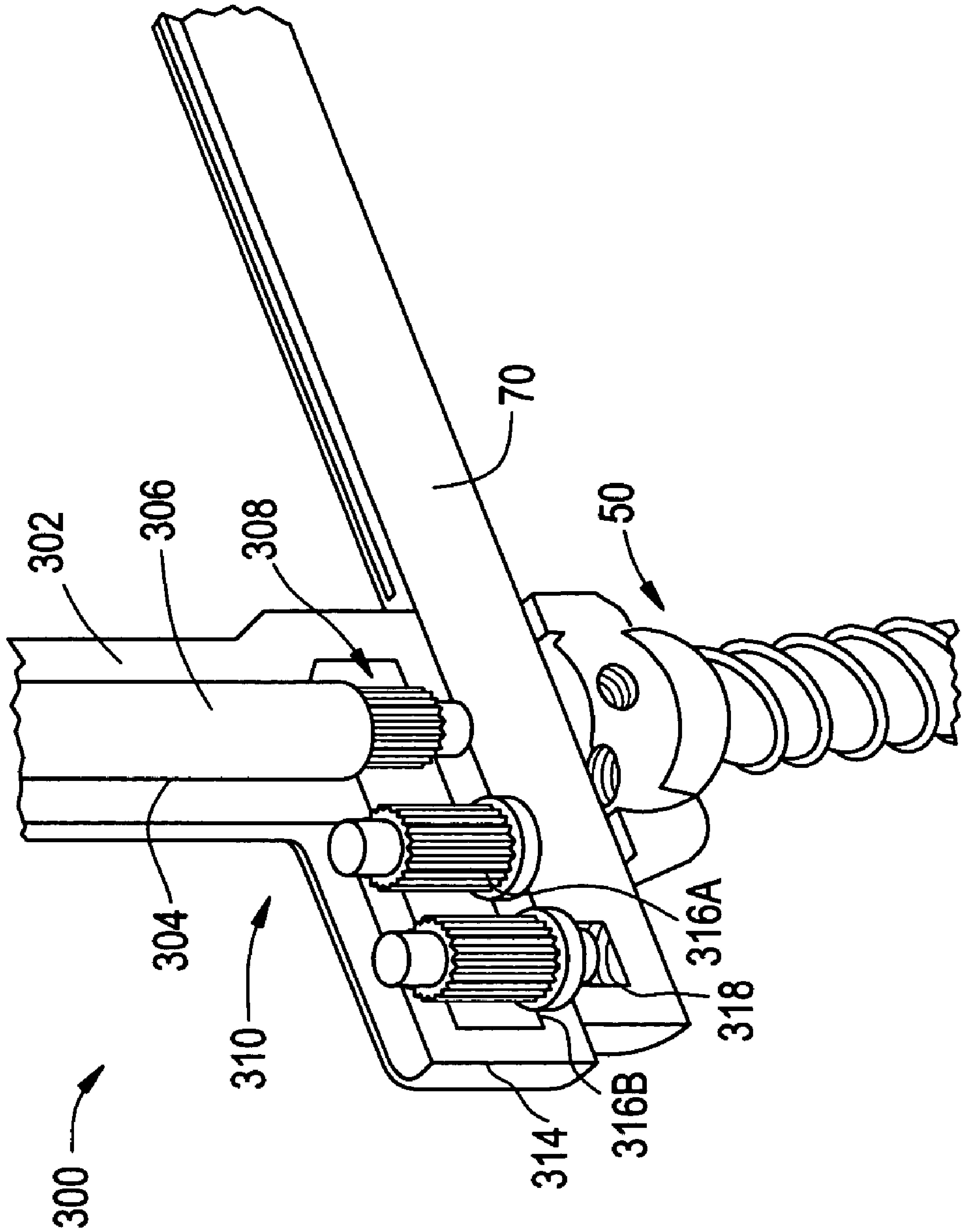

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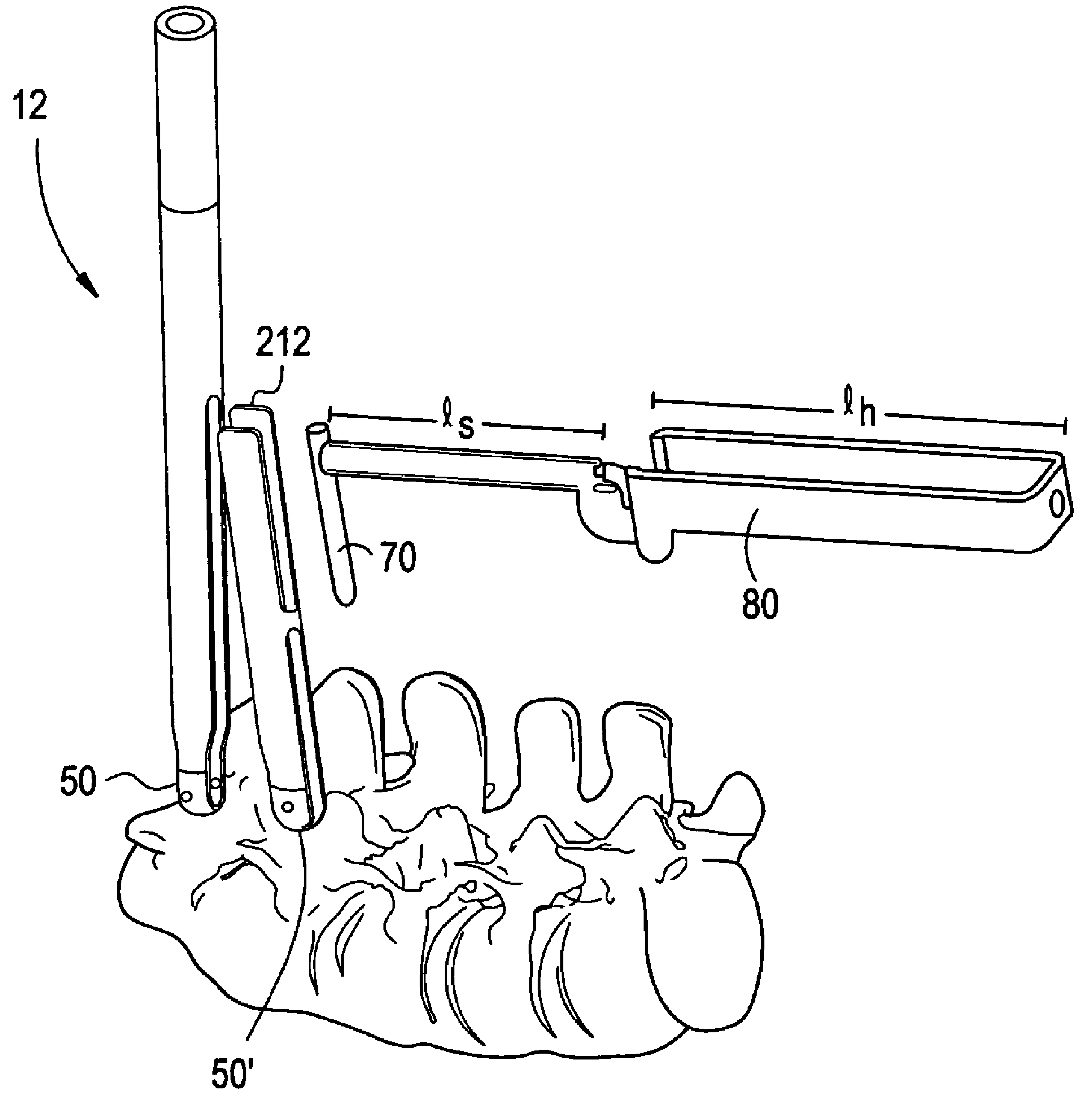

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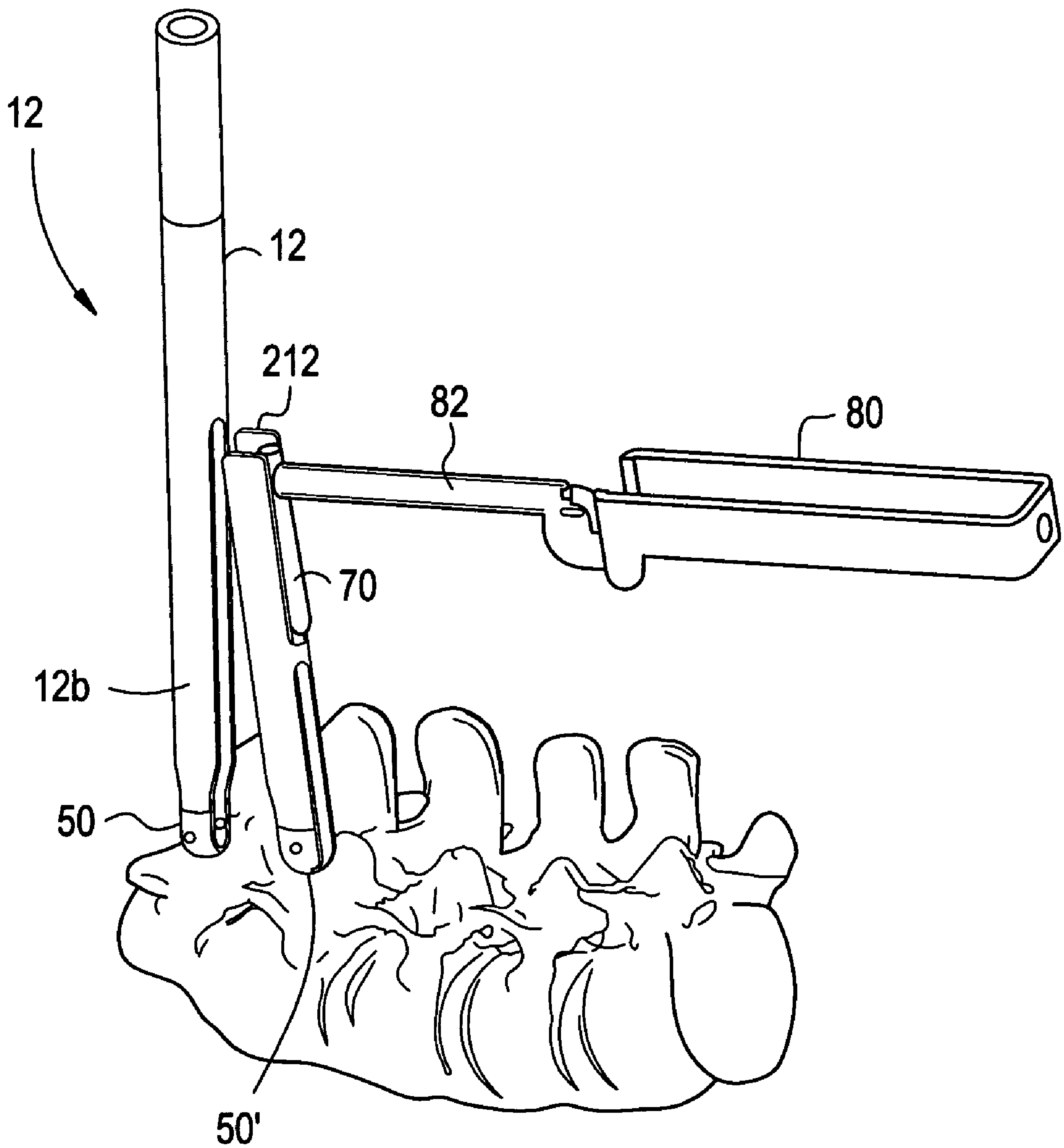

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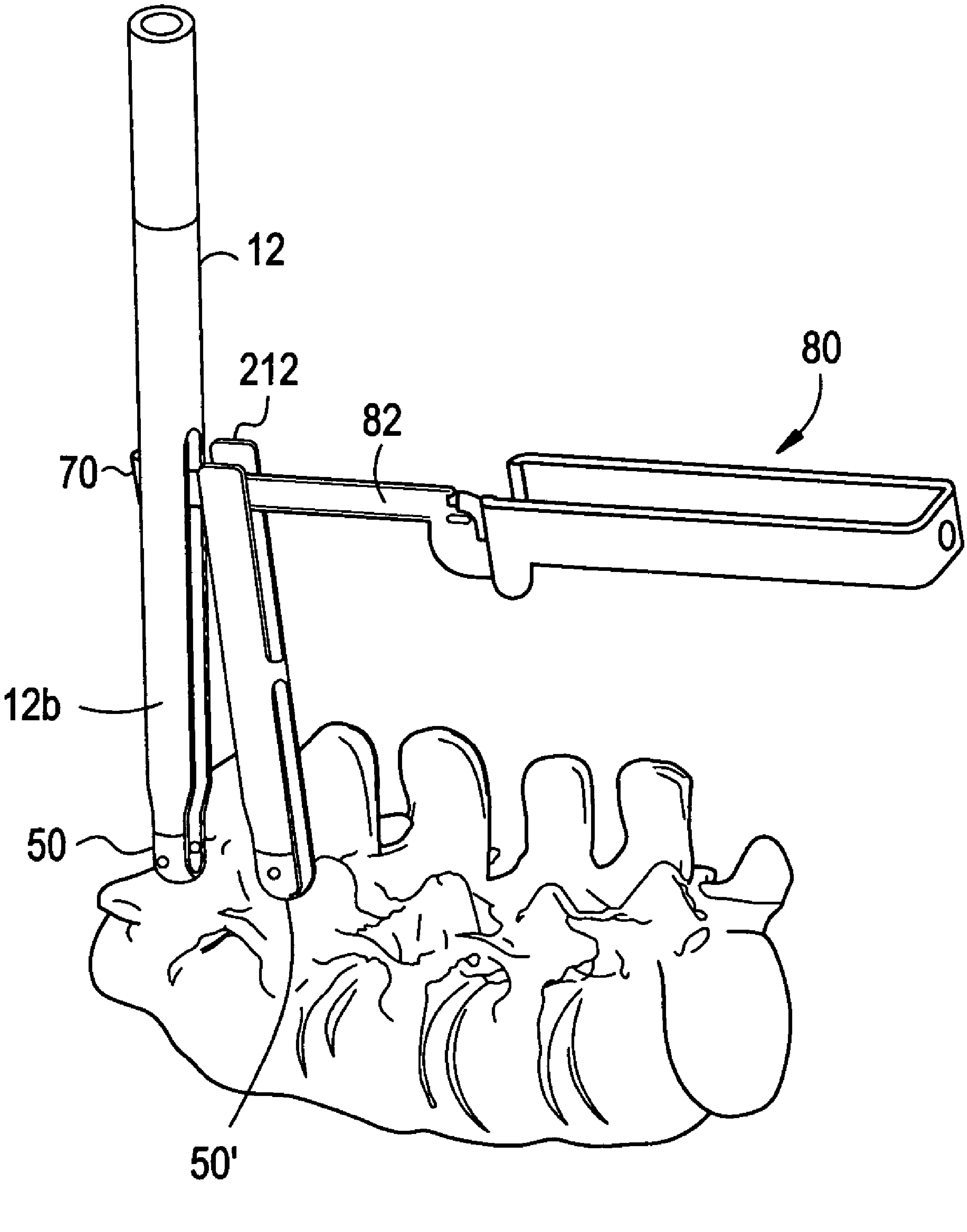

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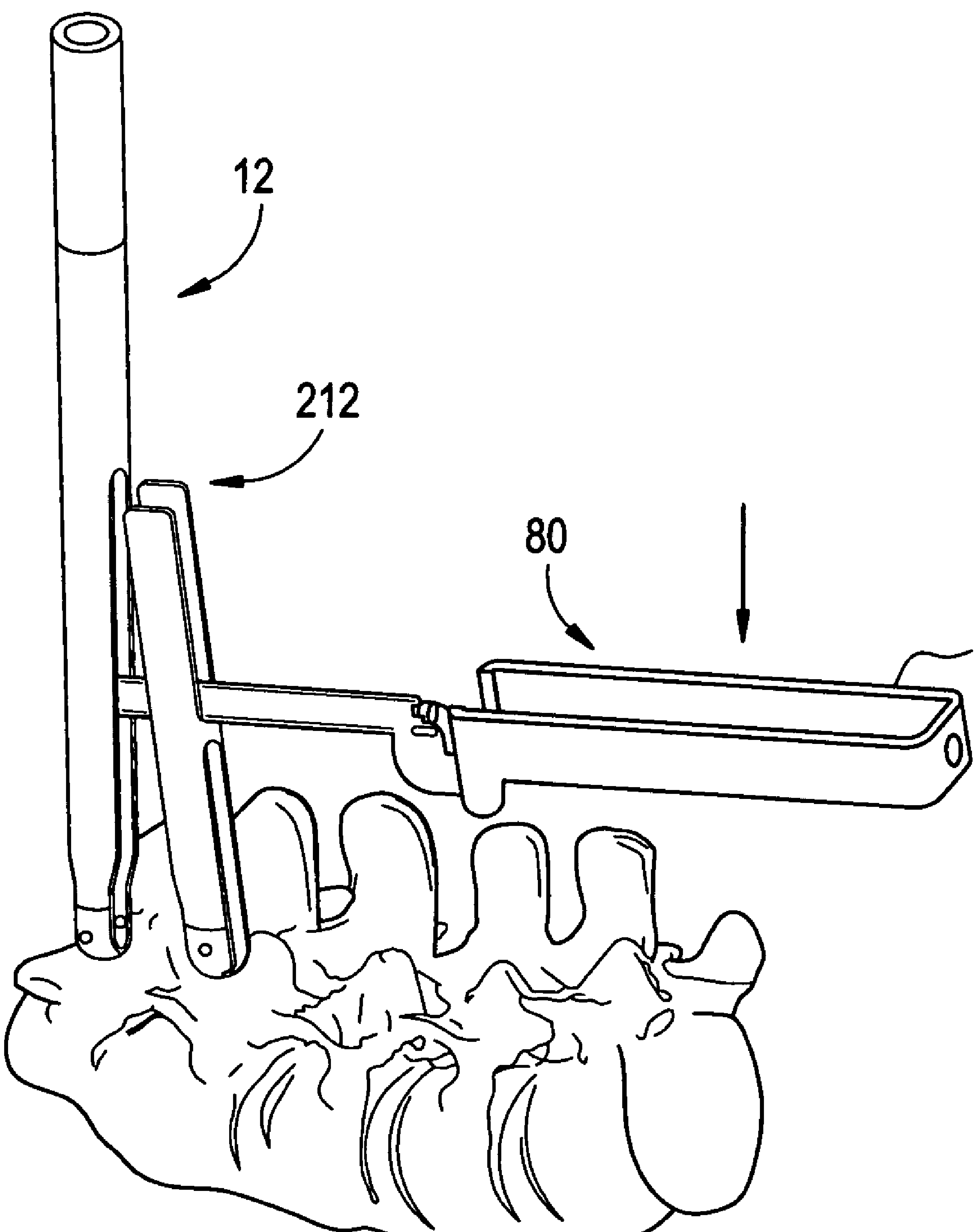

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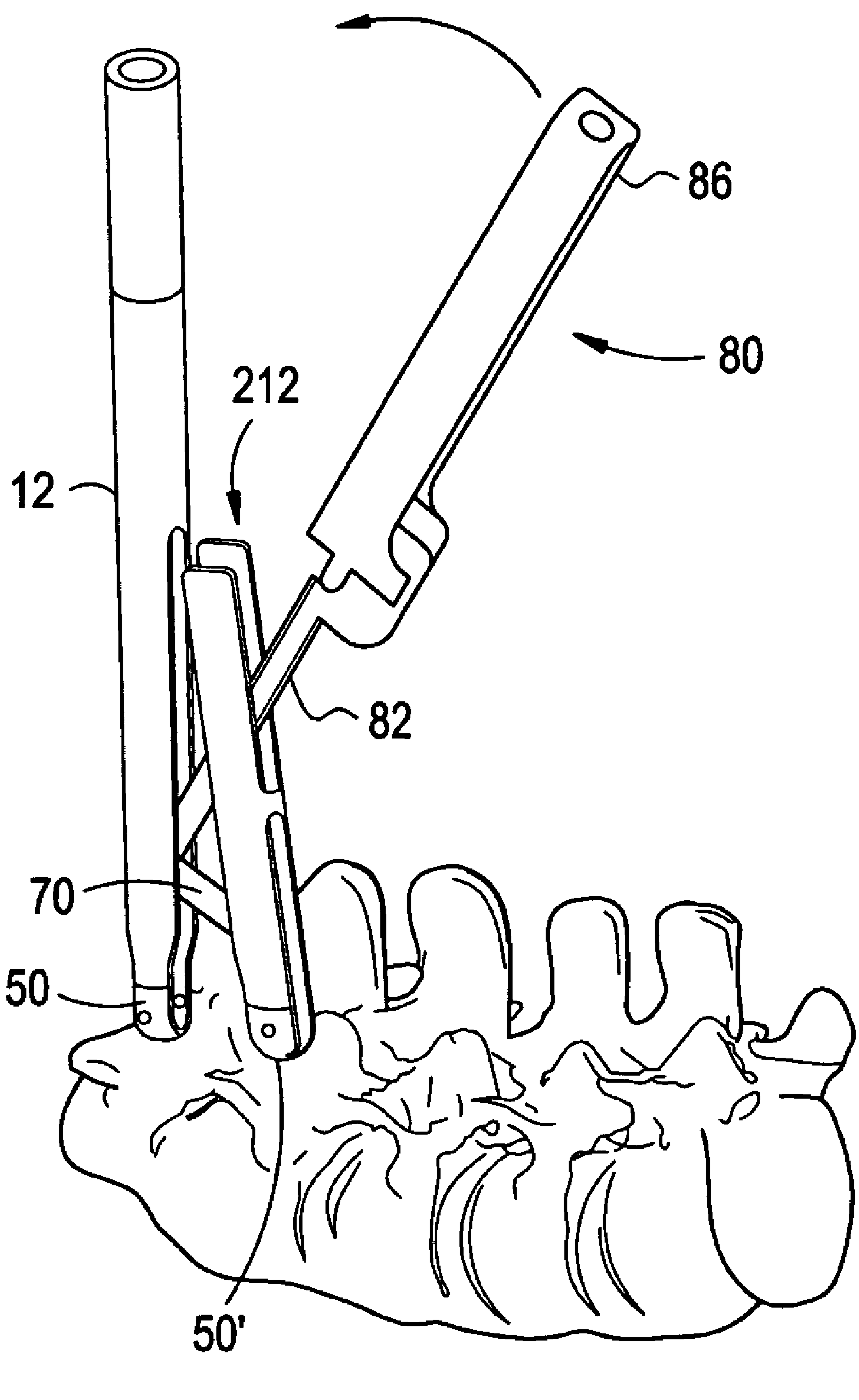

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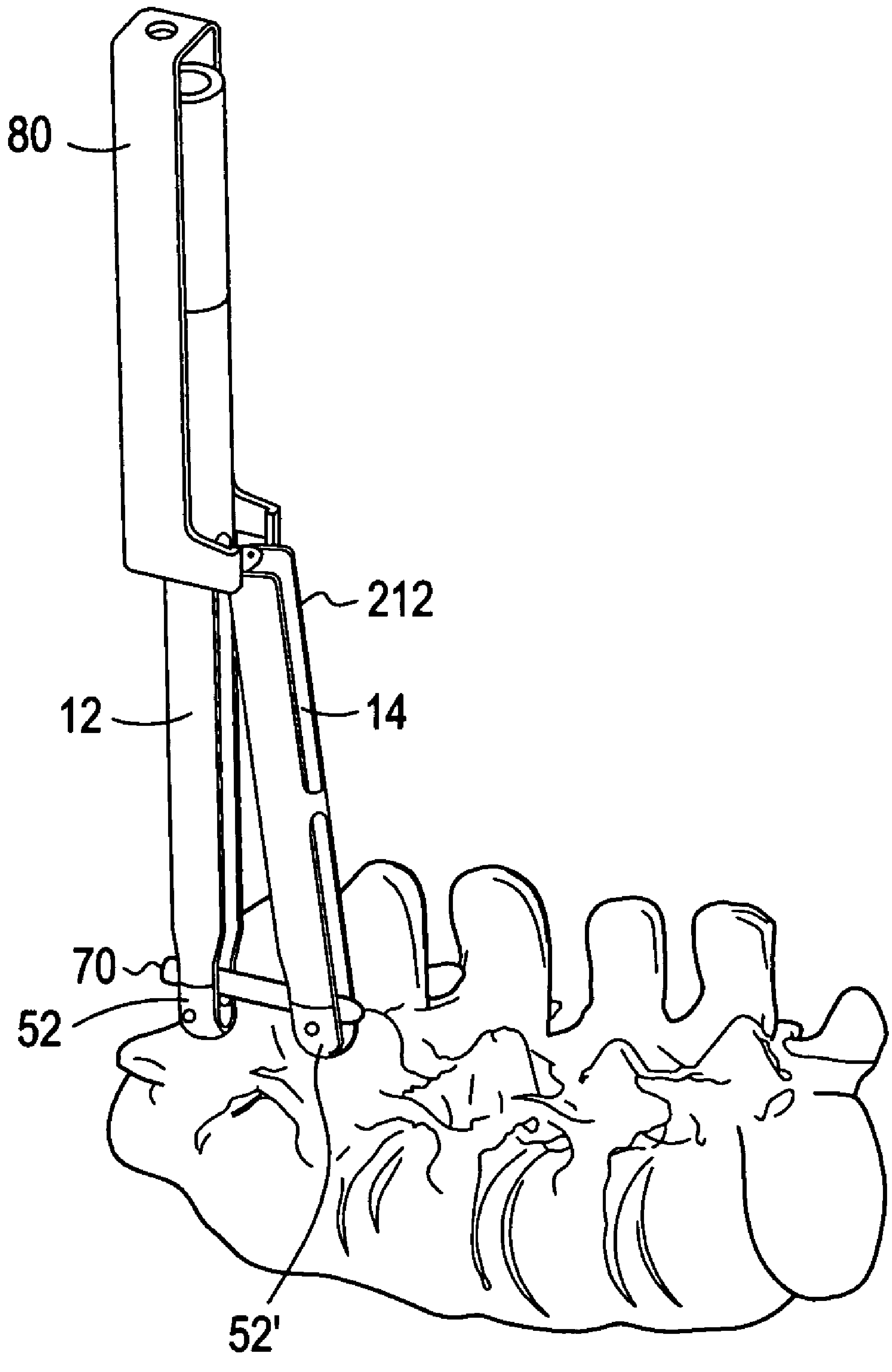

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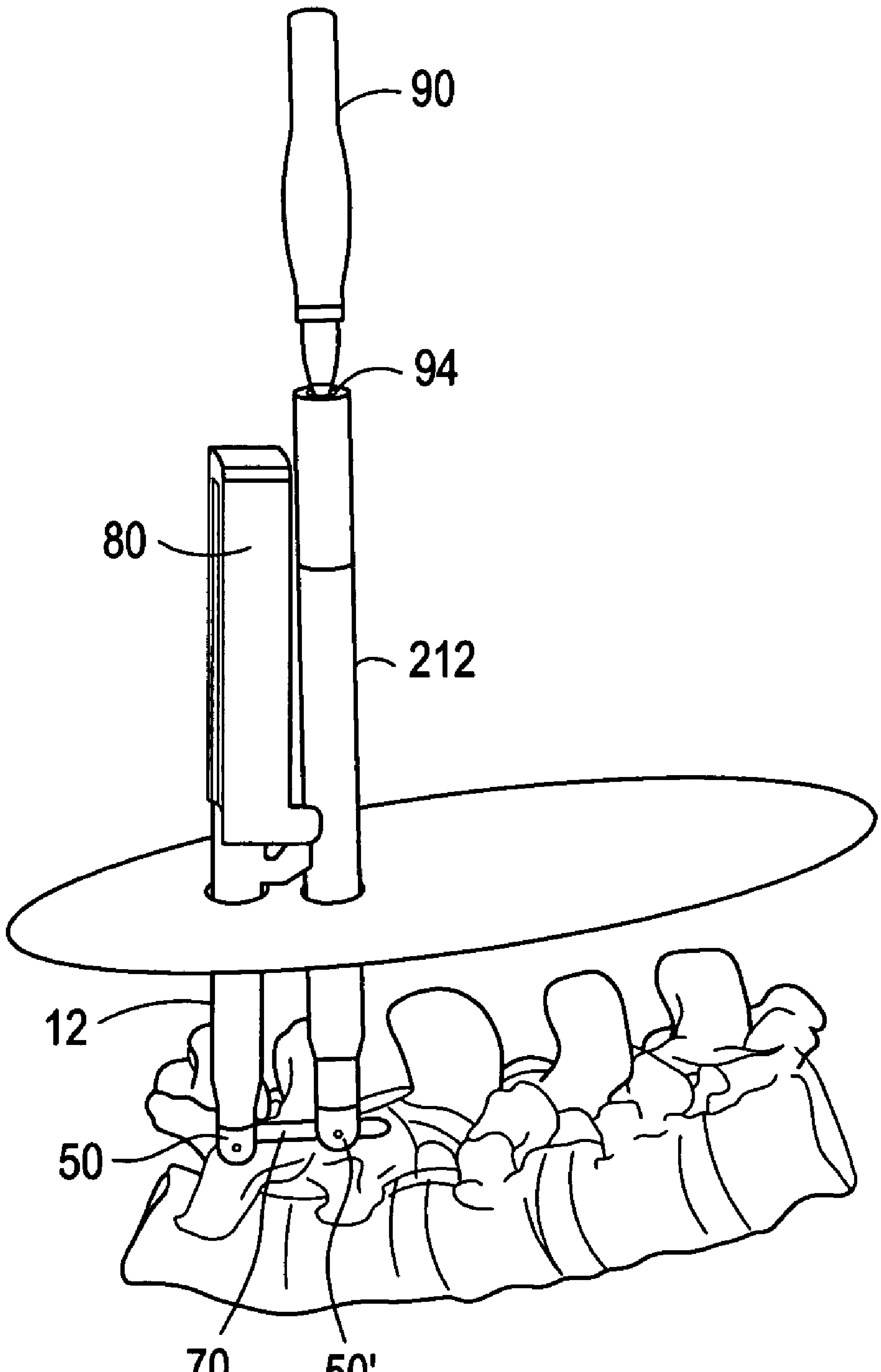

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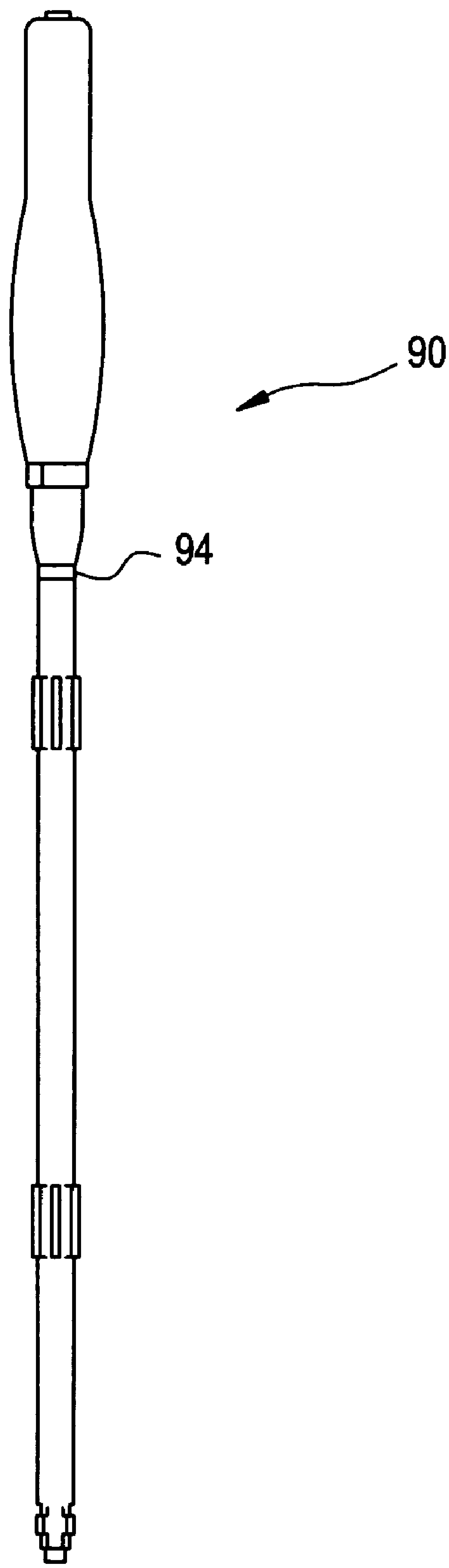

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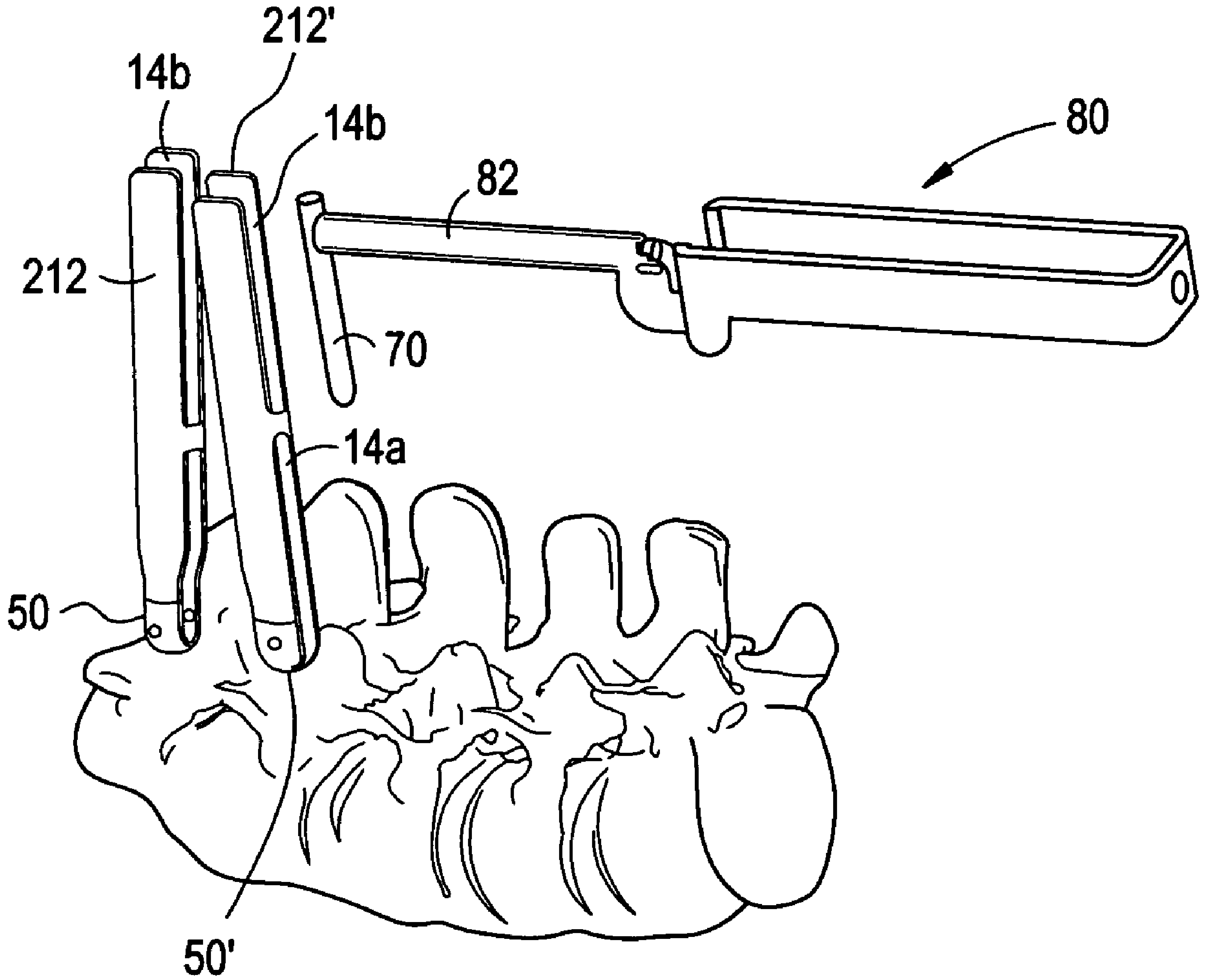

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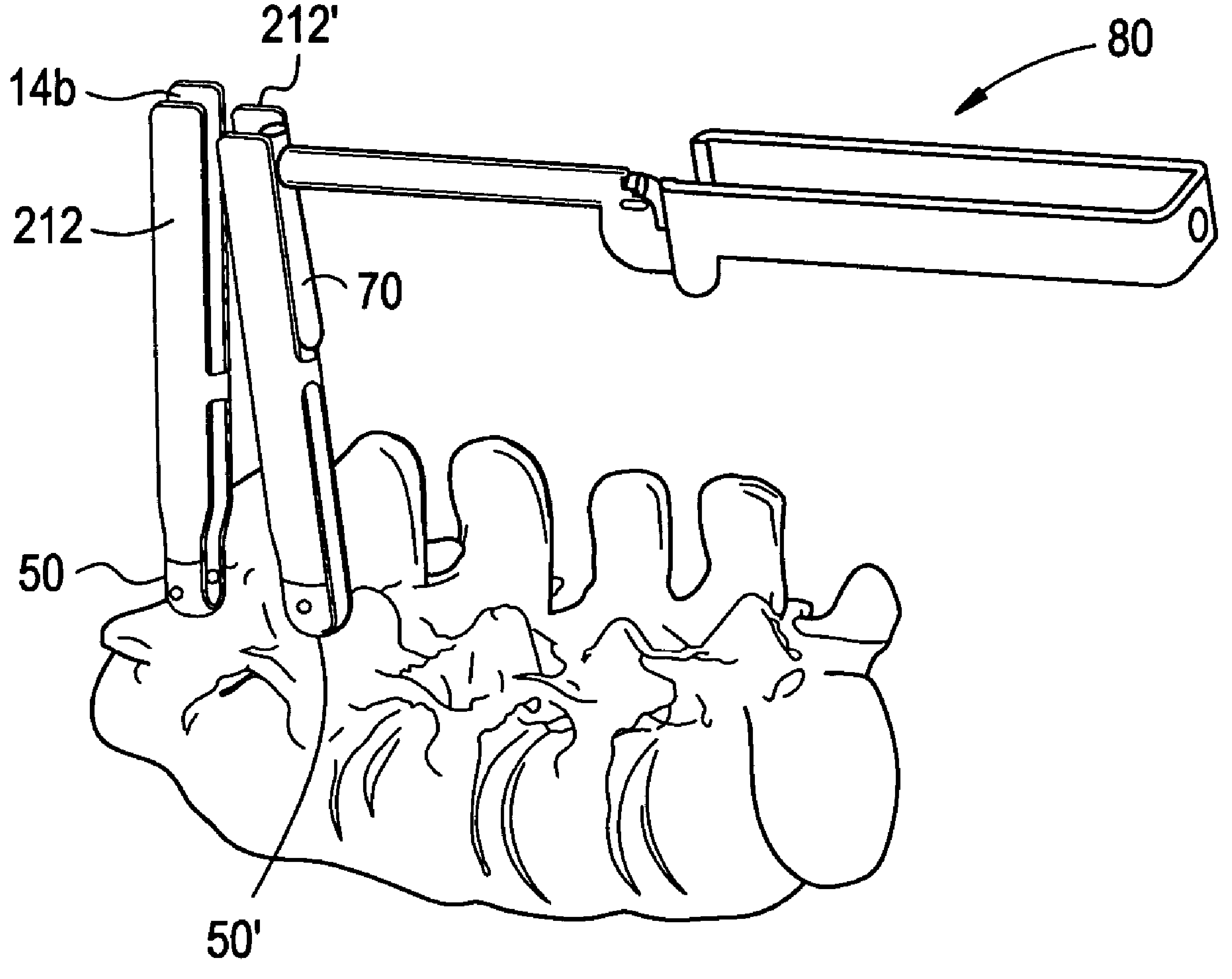

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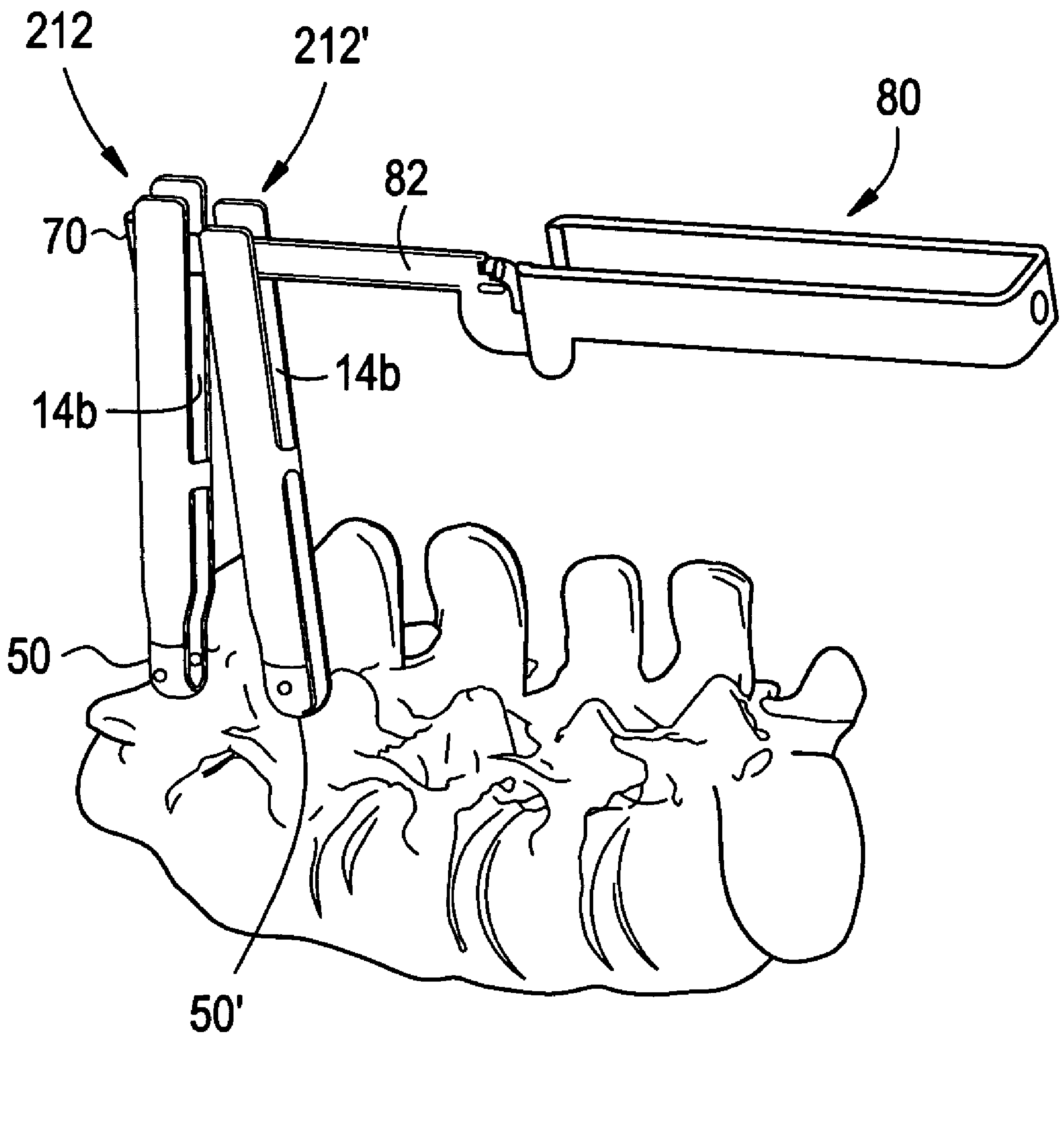

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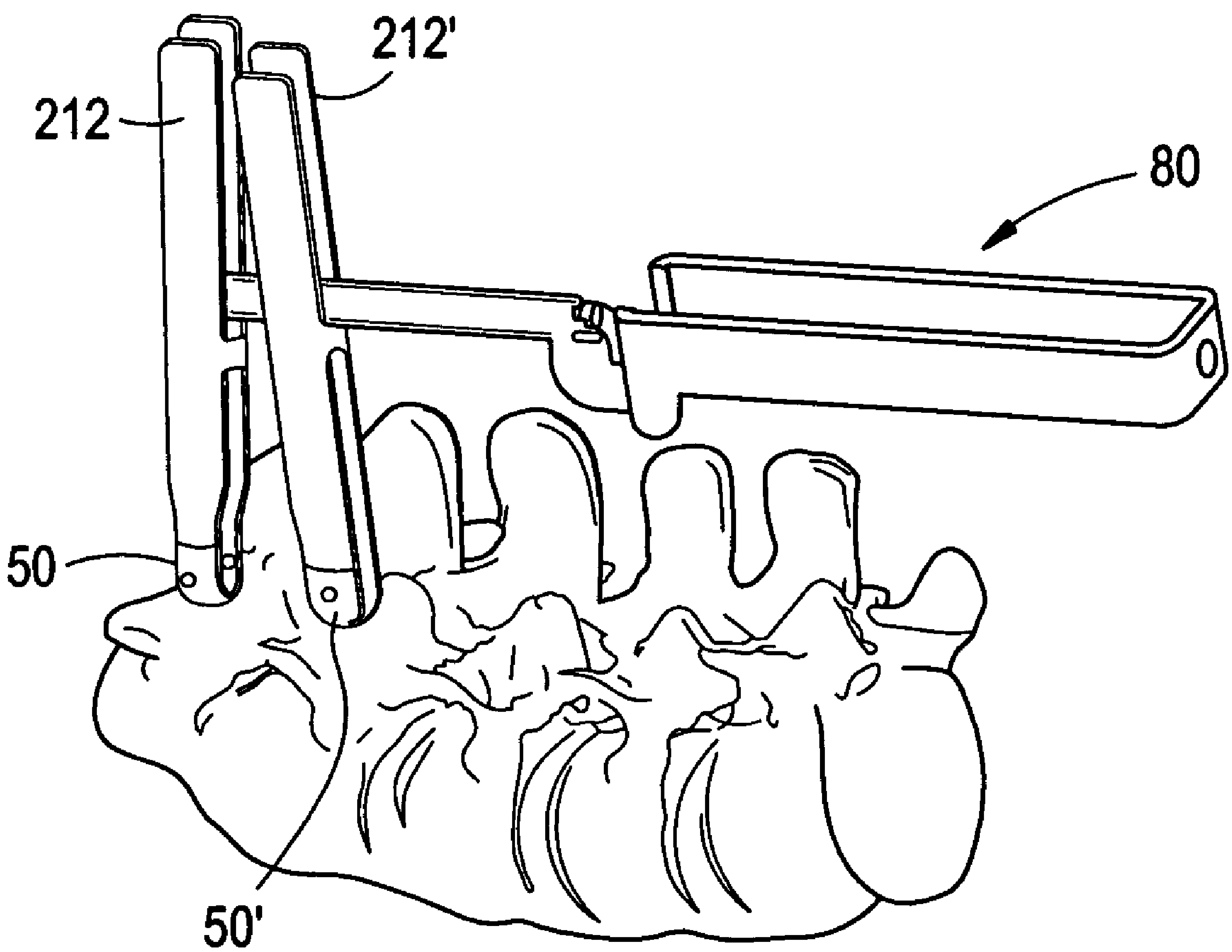

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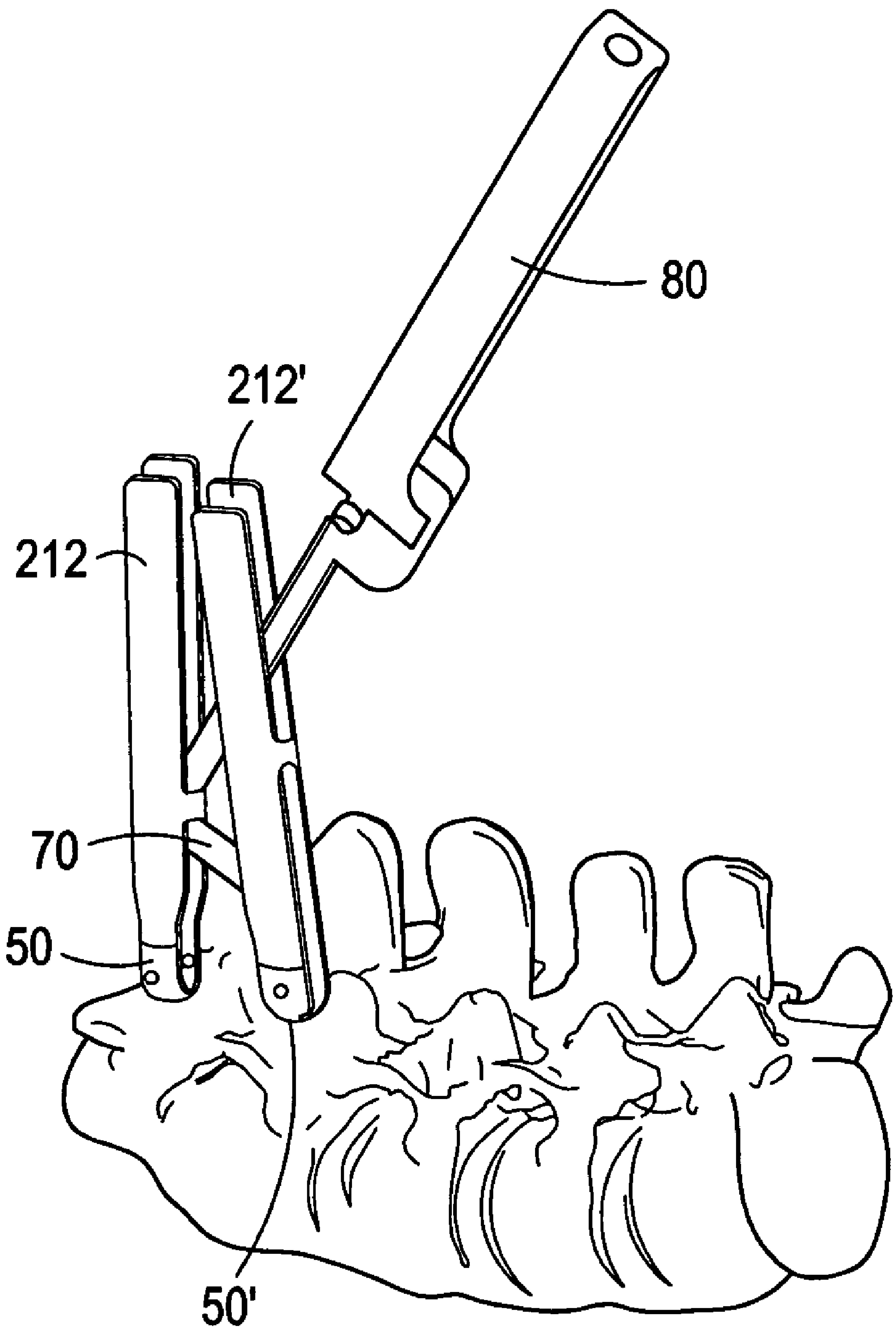

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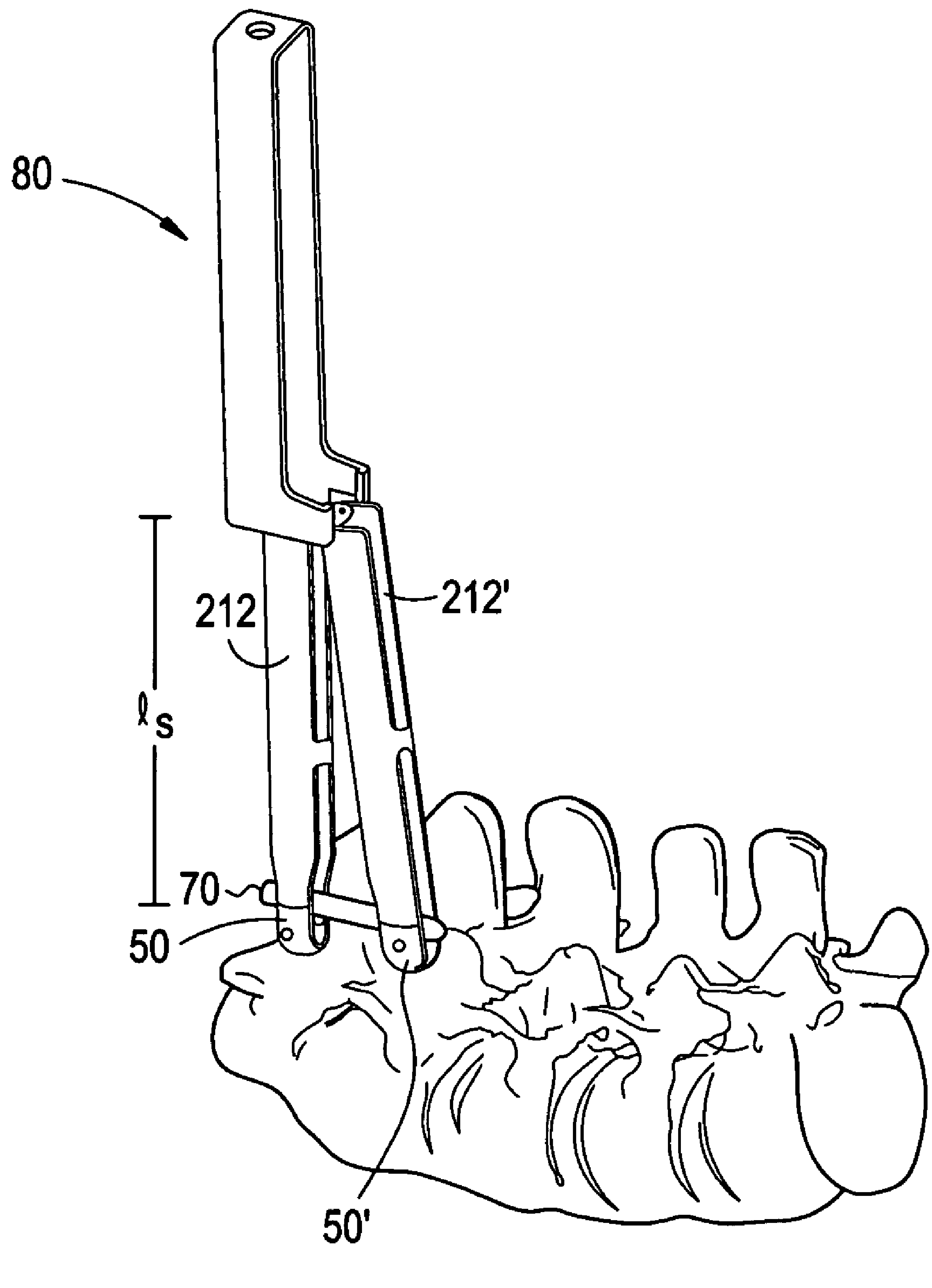

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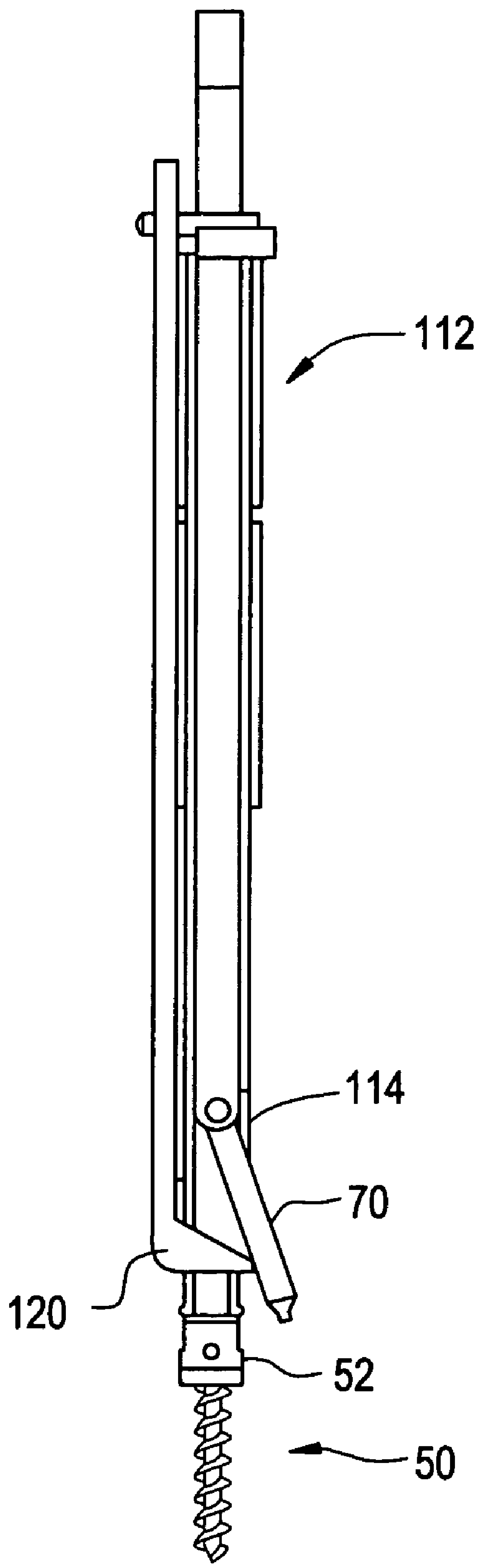

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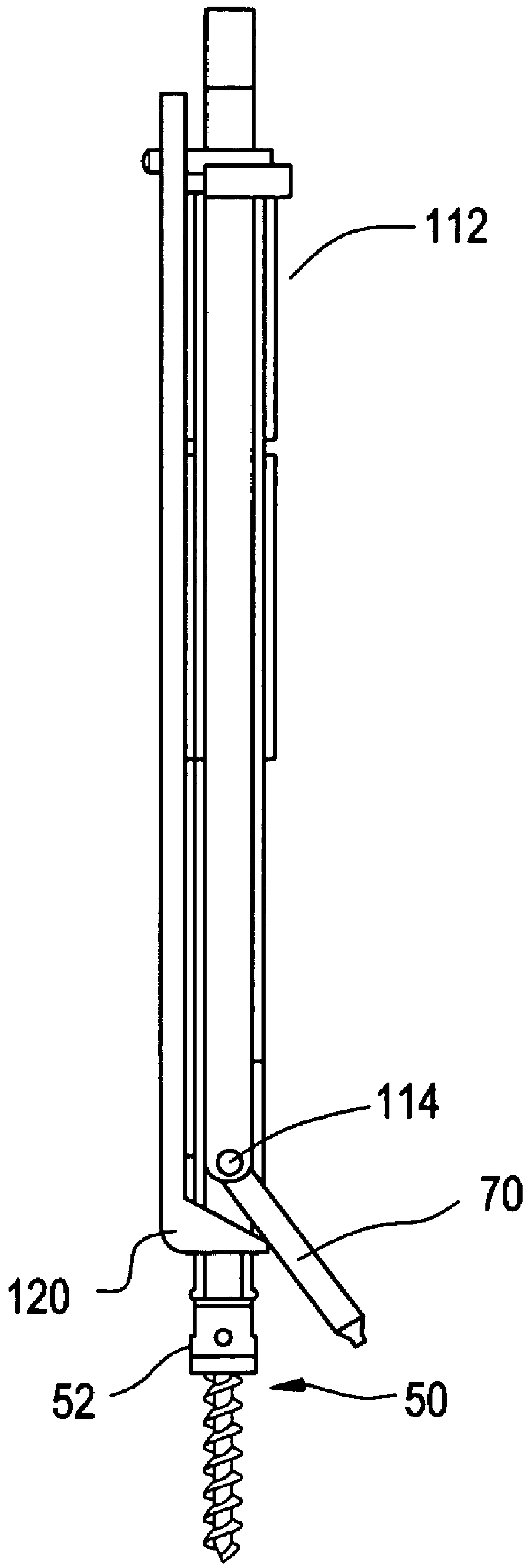

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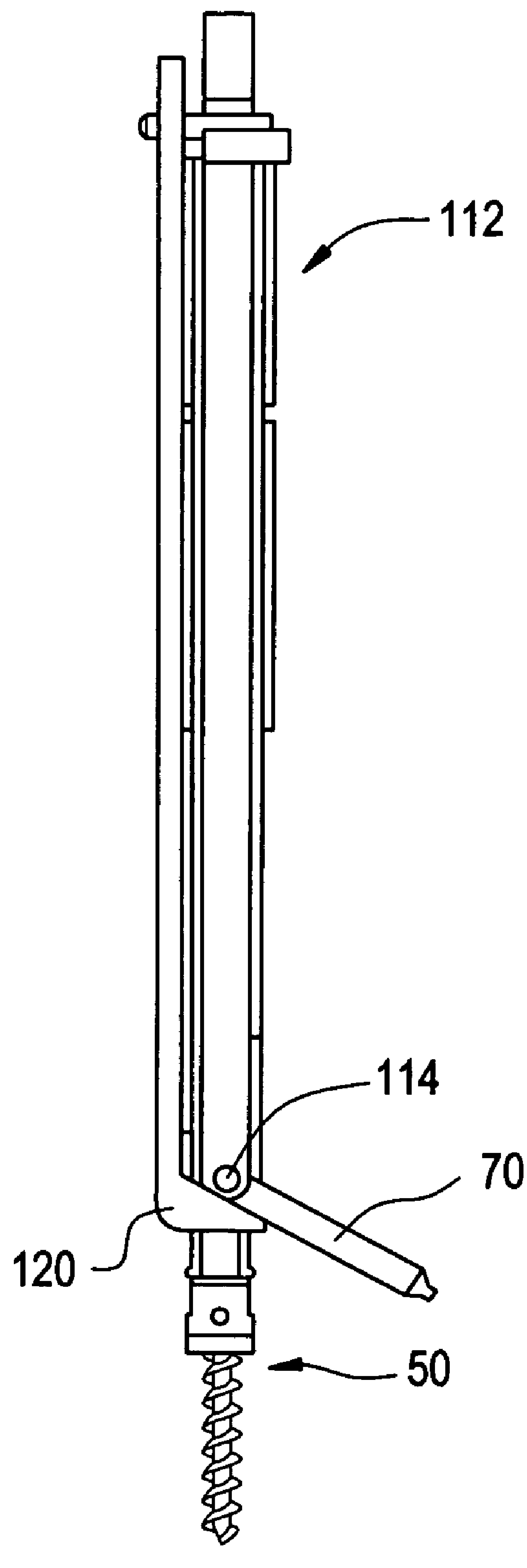

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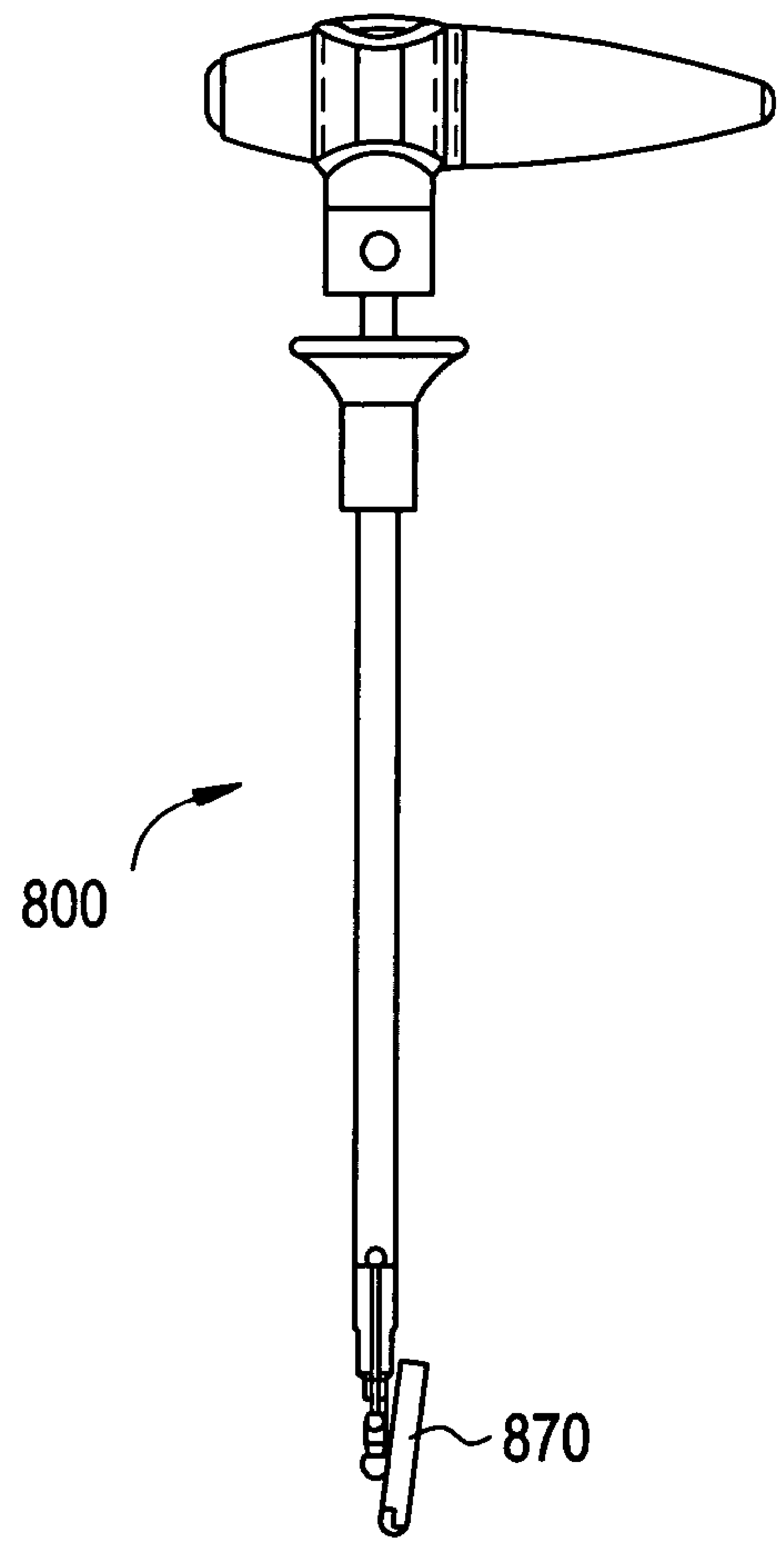

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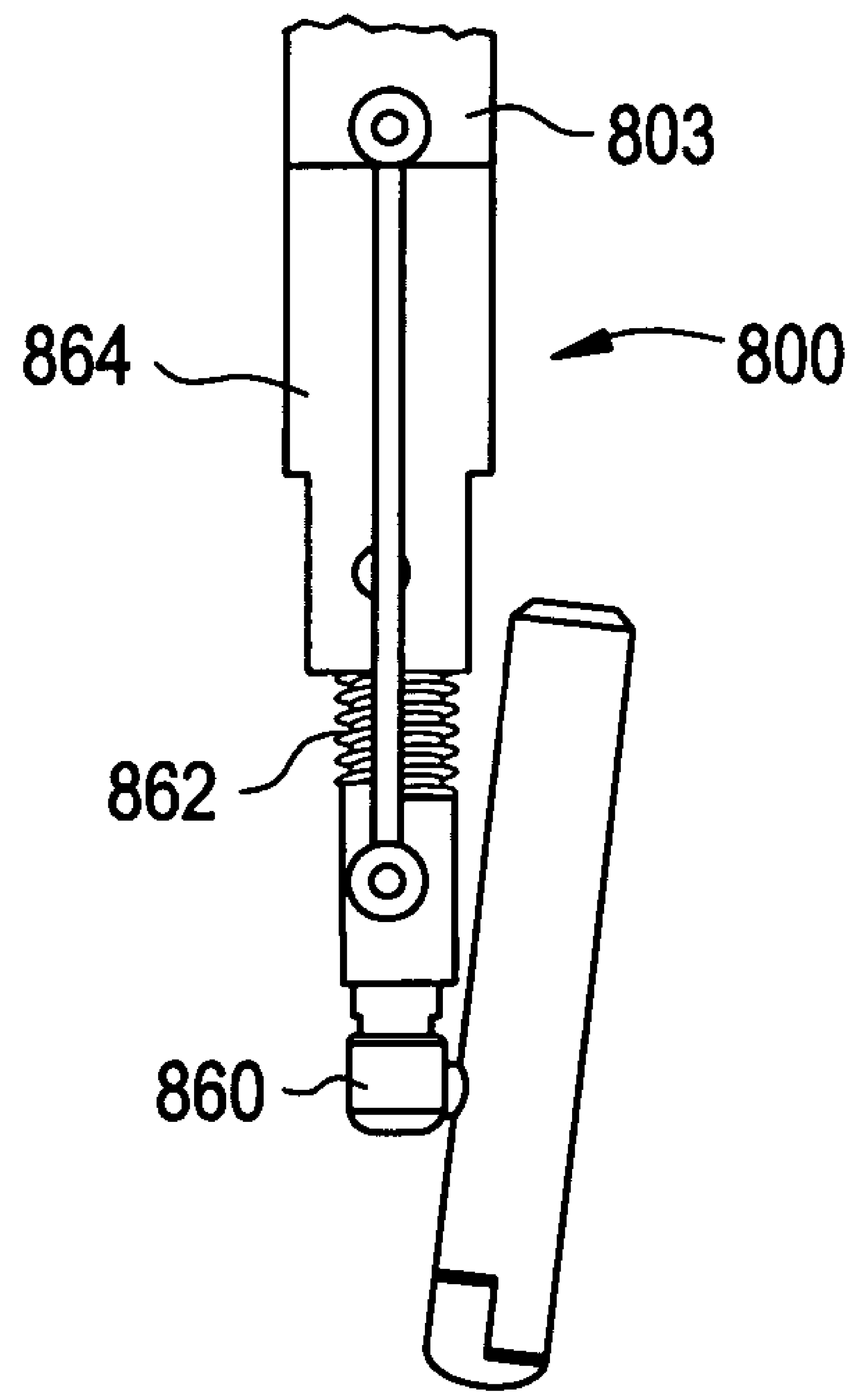

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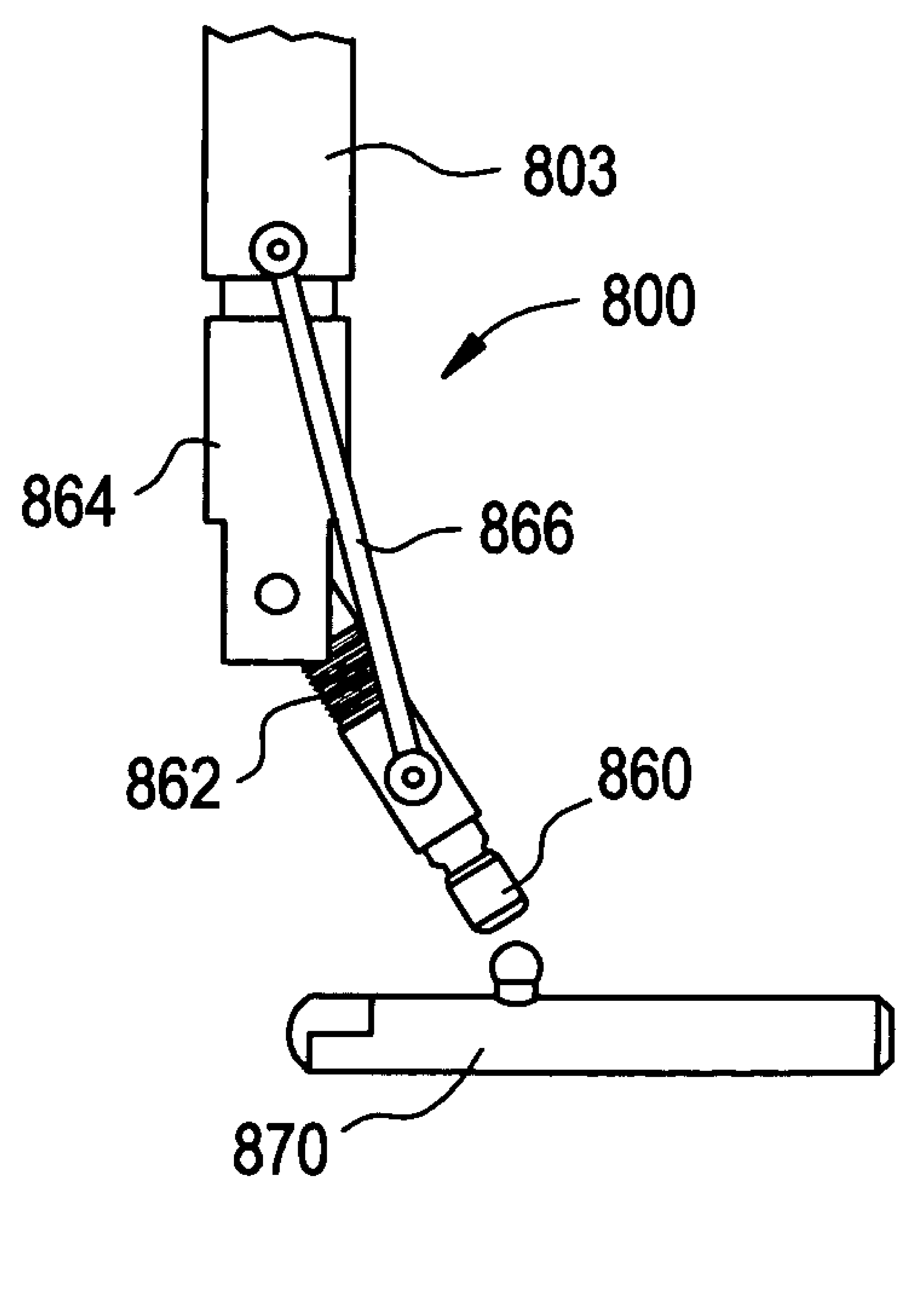
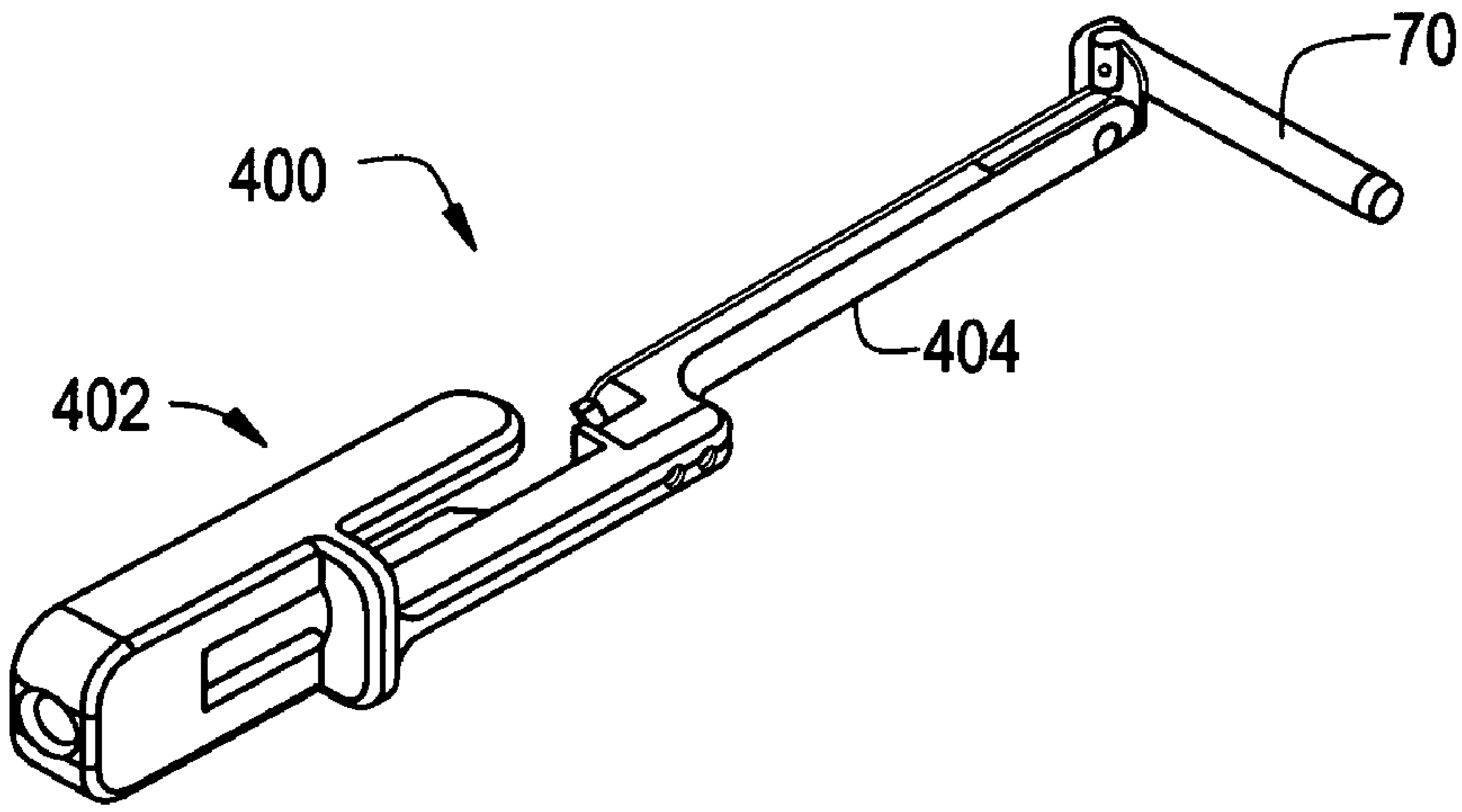


FIG. 32A



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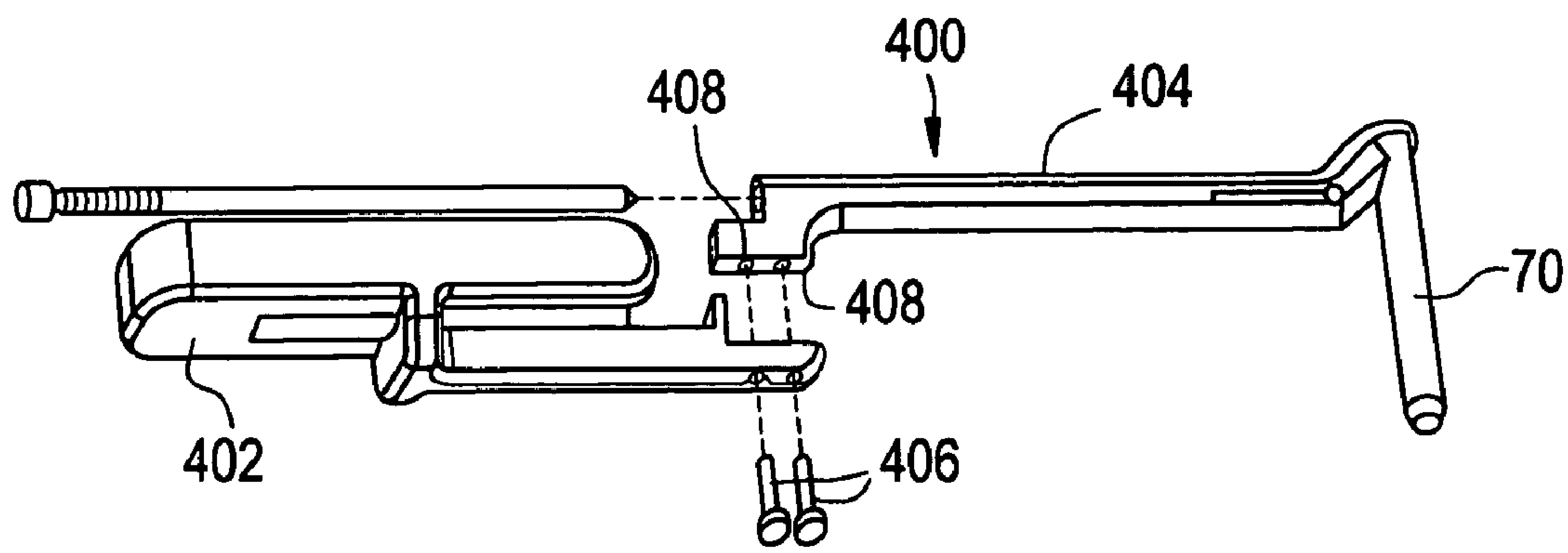
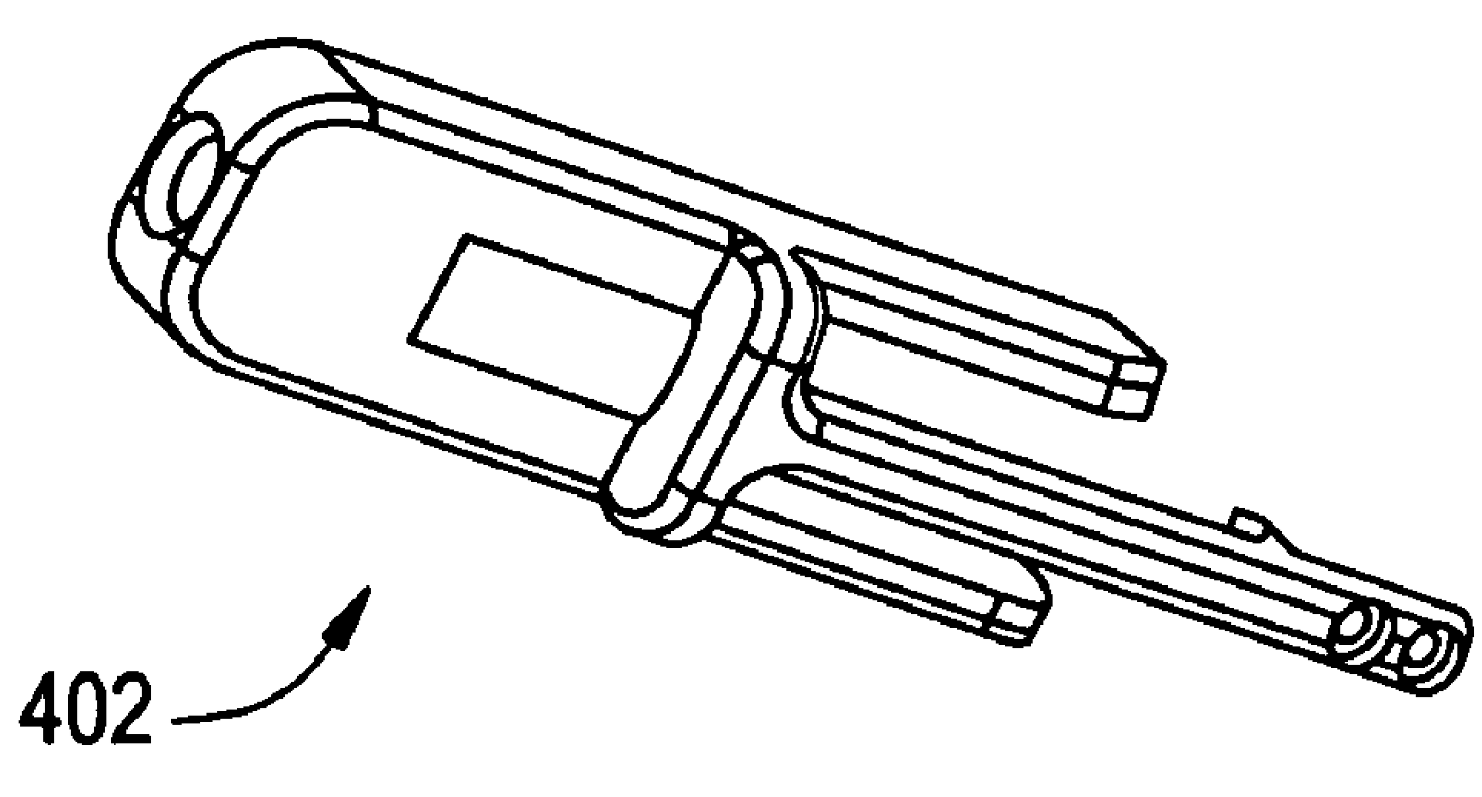


FIG. 33A



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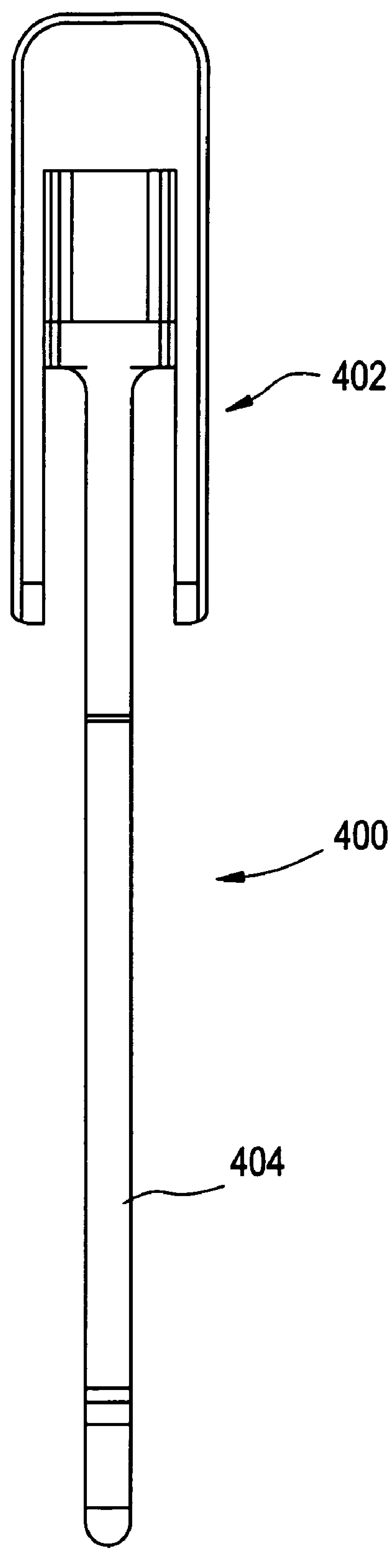

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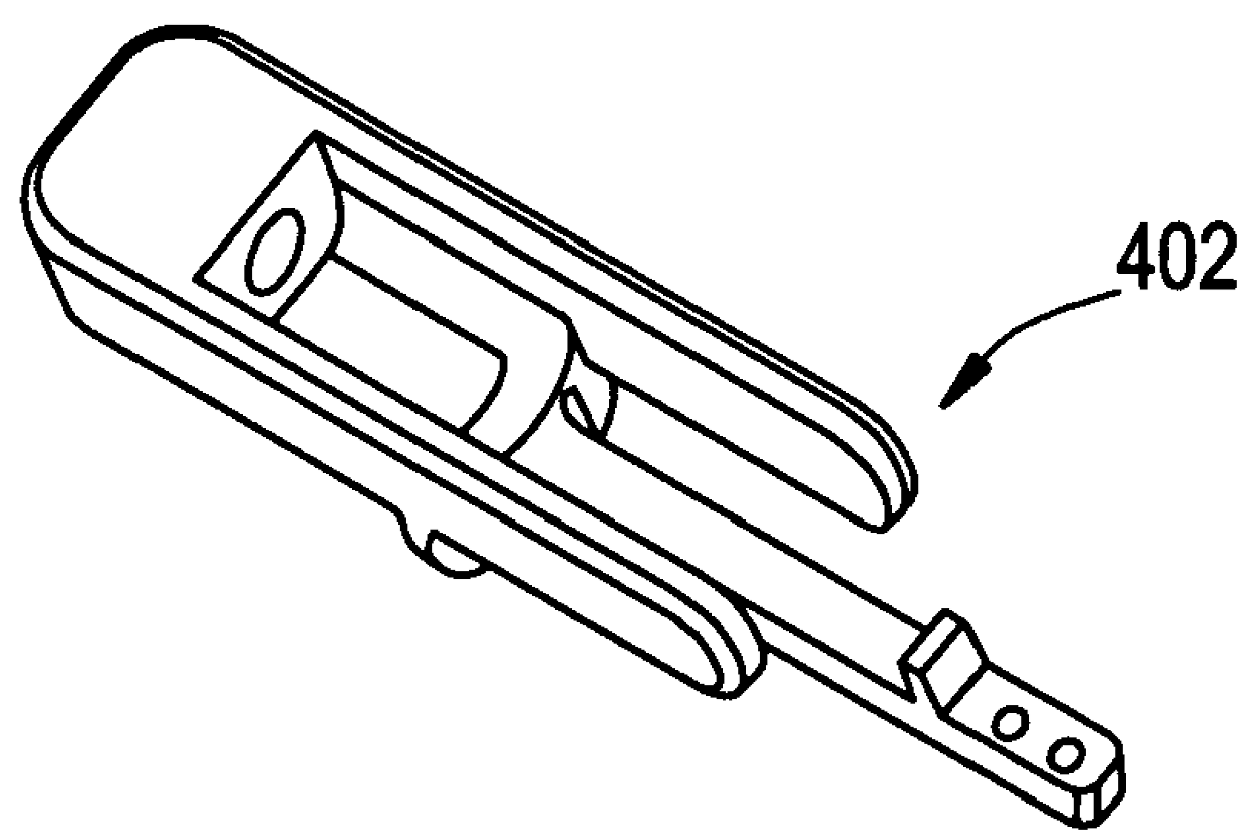

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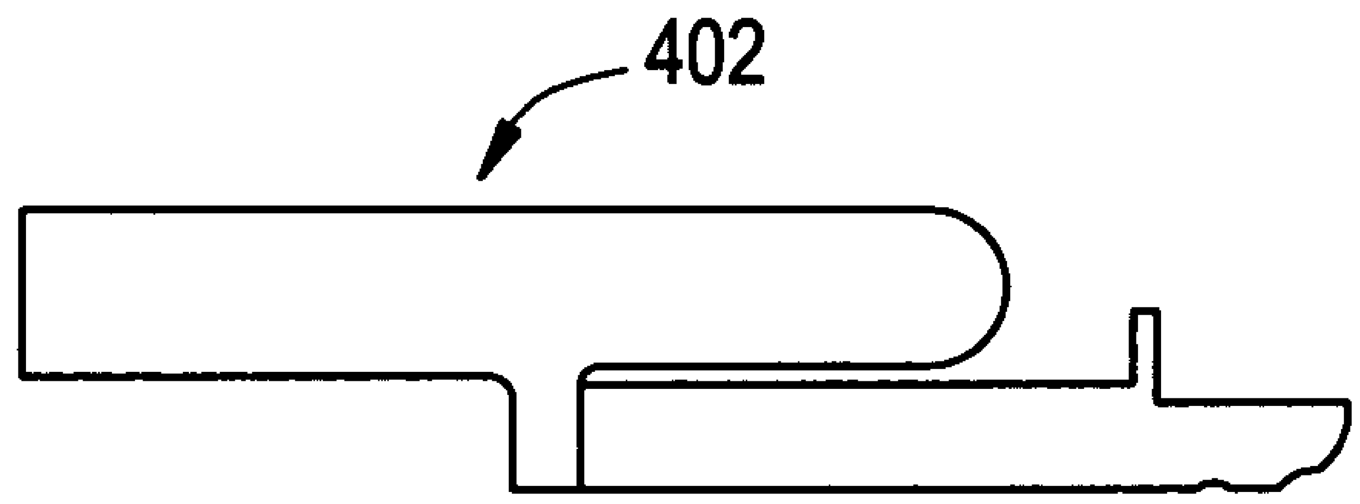
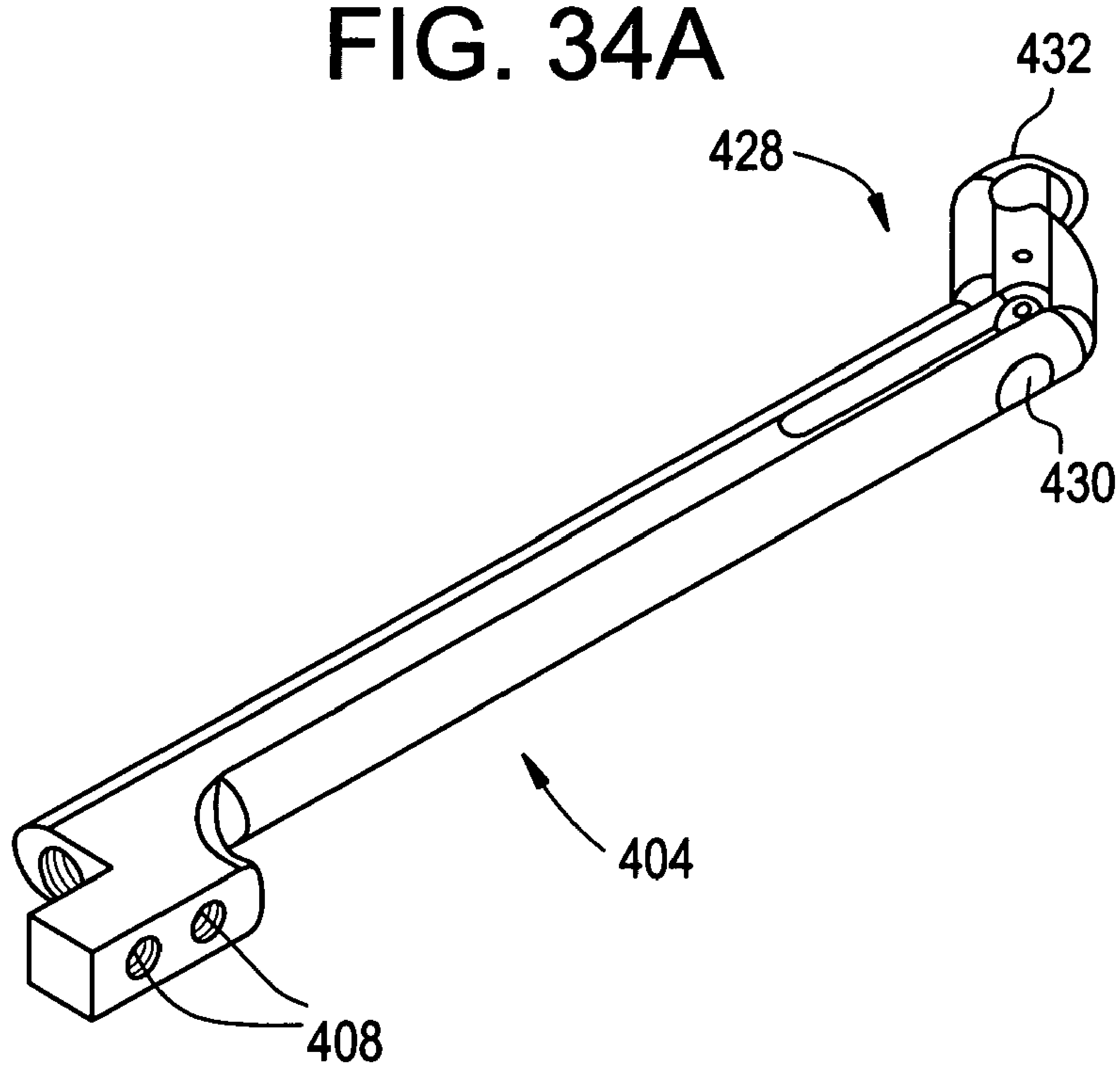


FIG. 34A



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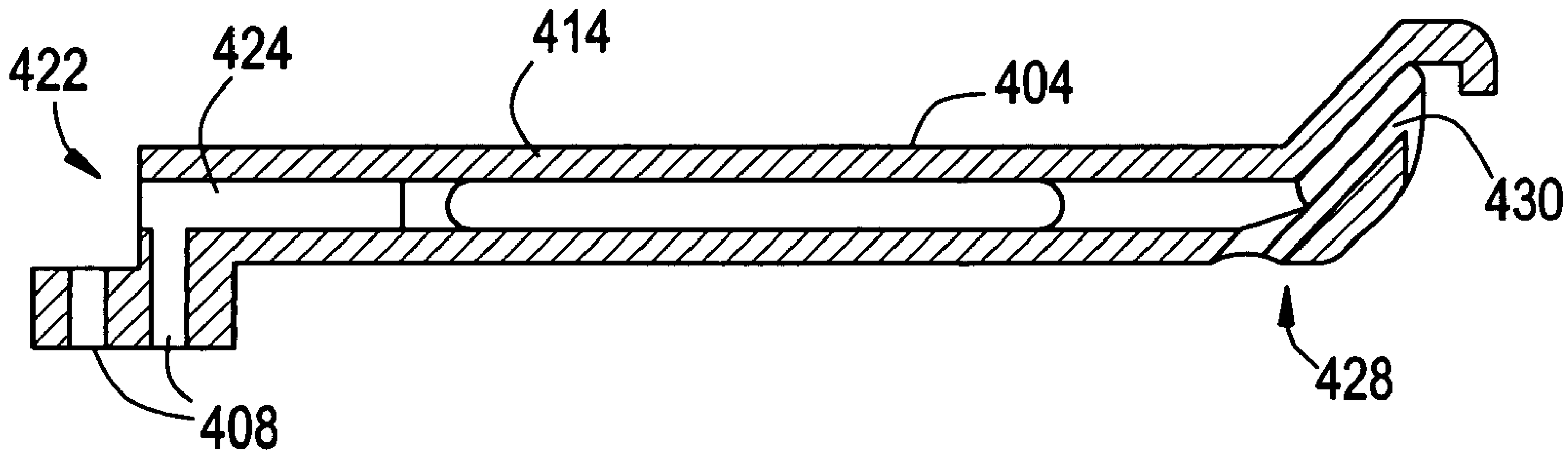
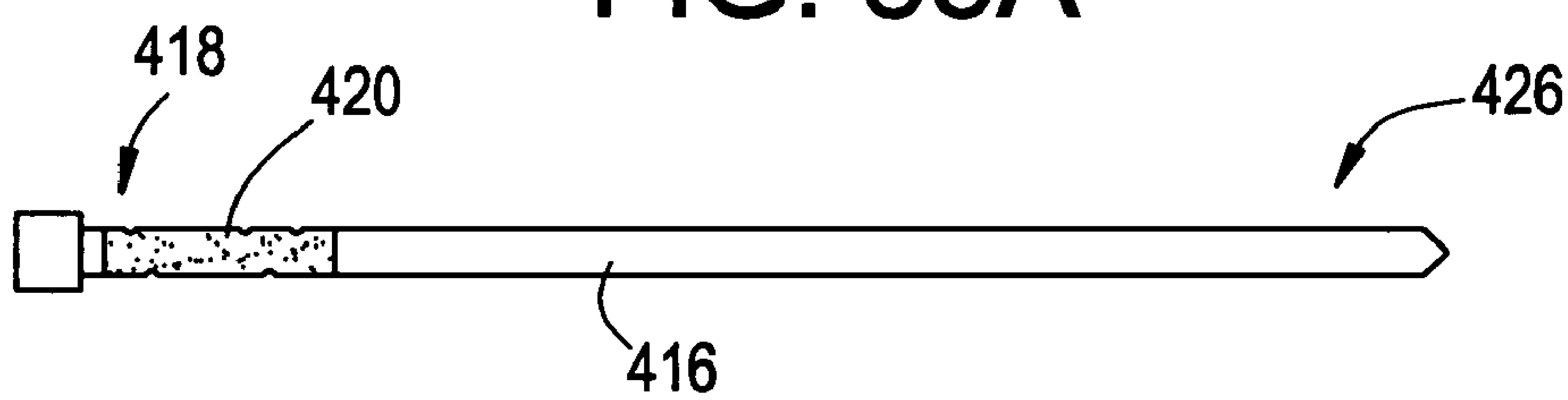


FIG. 35A



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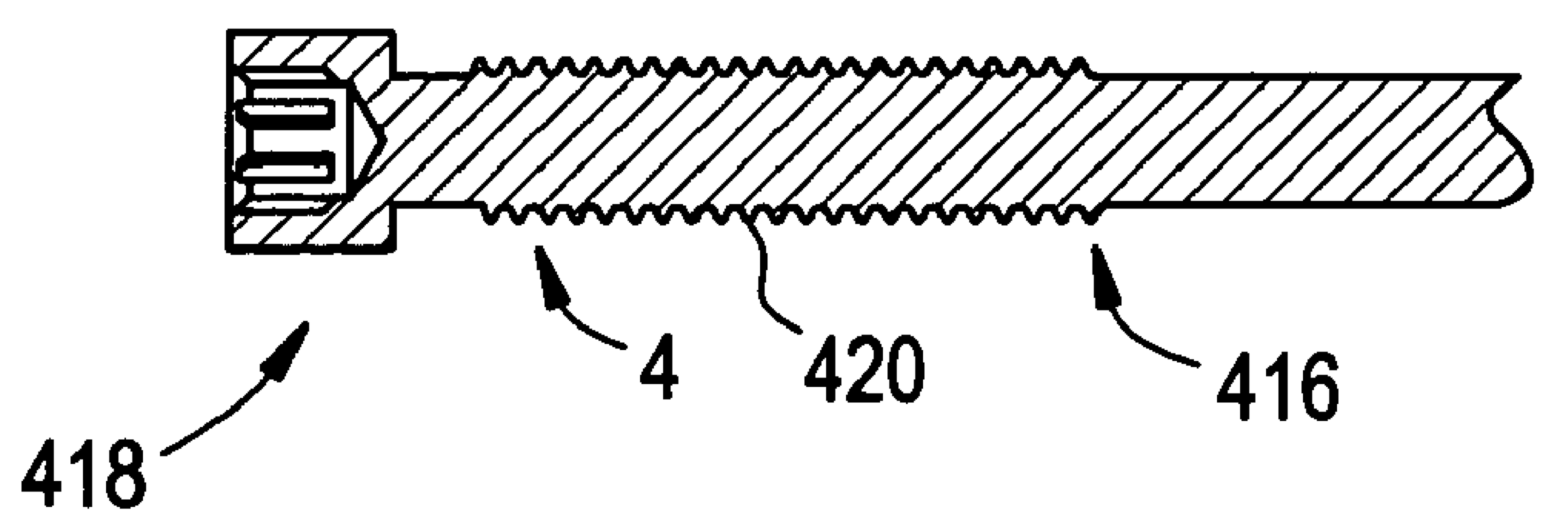

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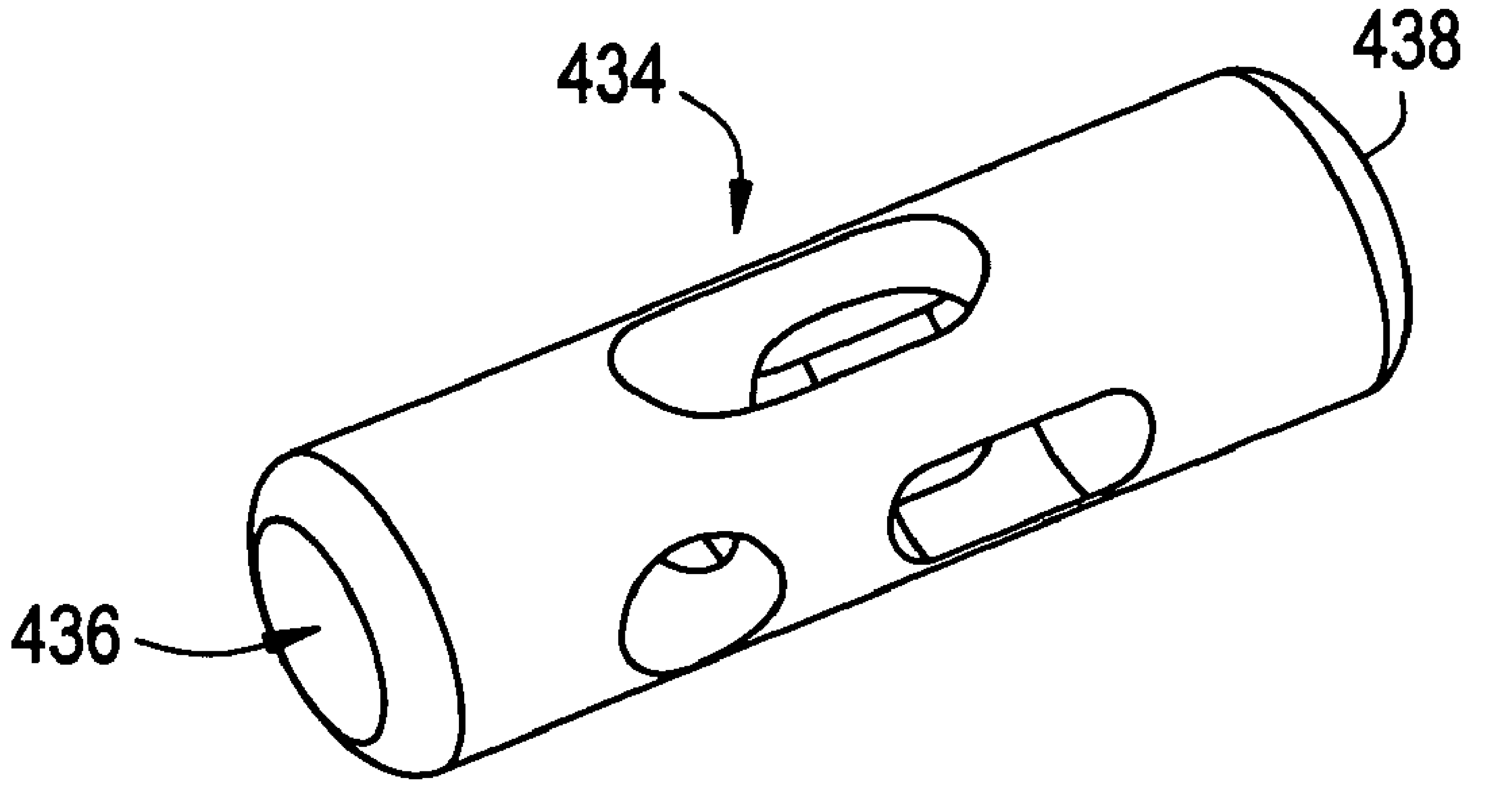


FIG. 37

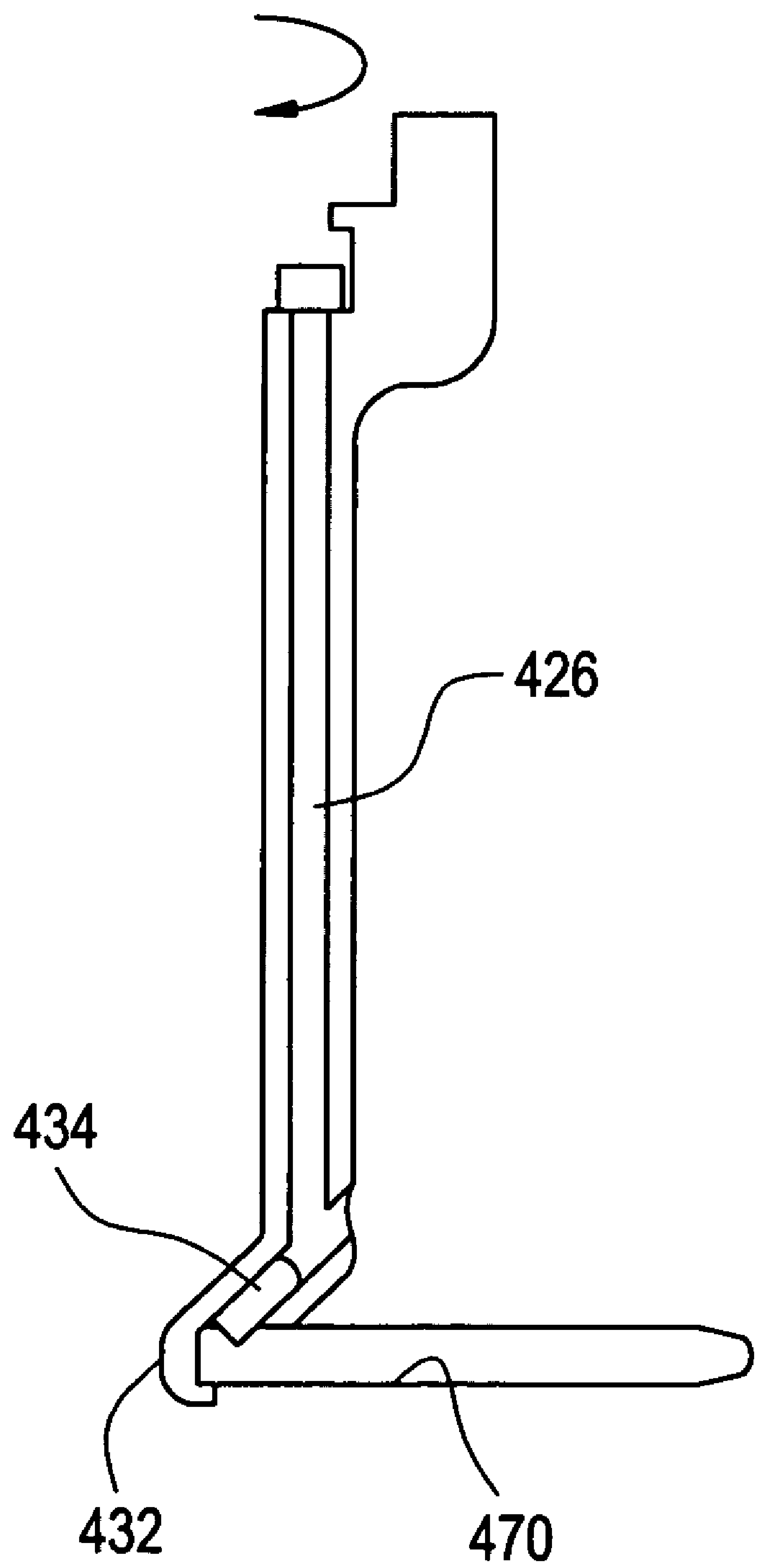
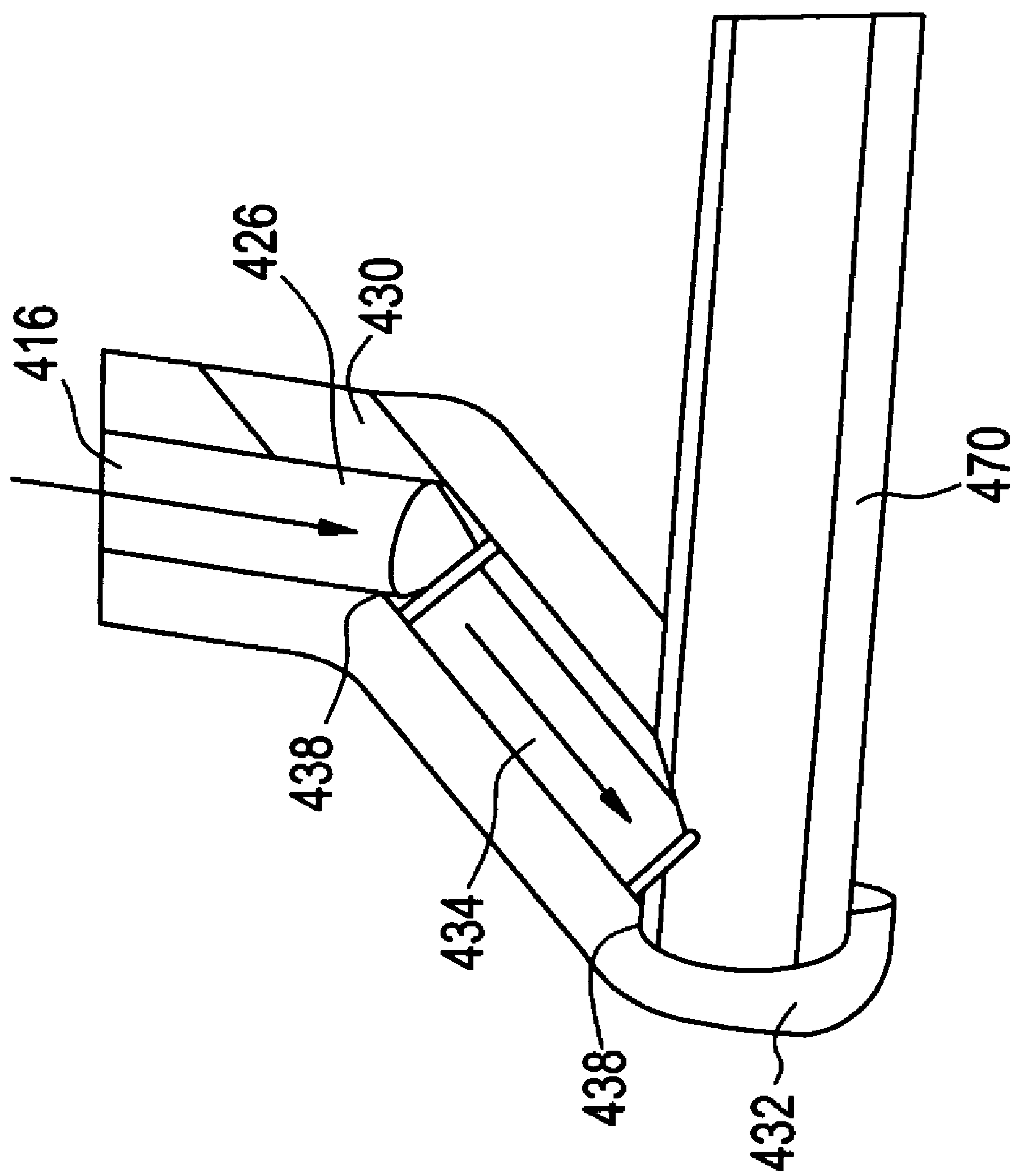


FIG. 38A



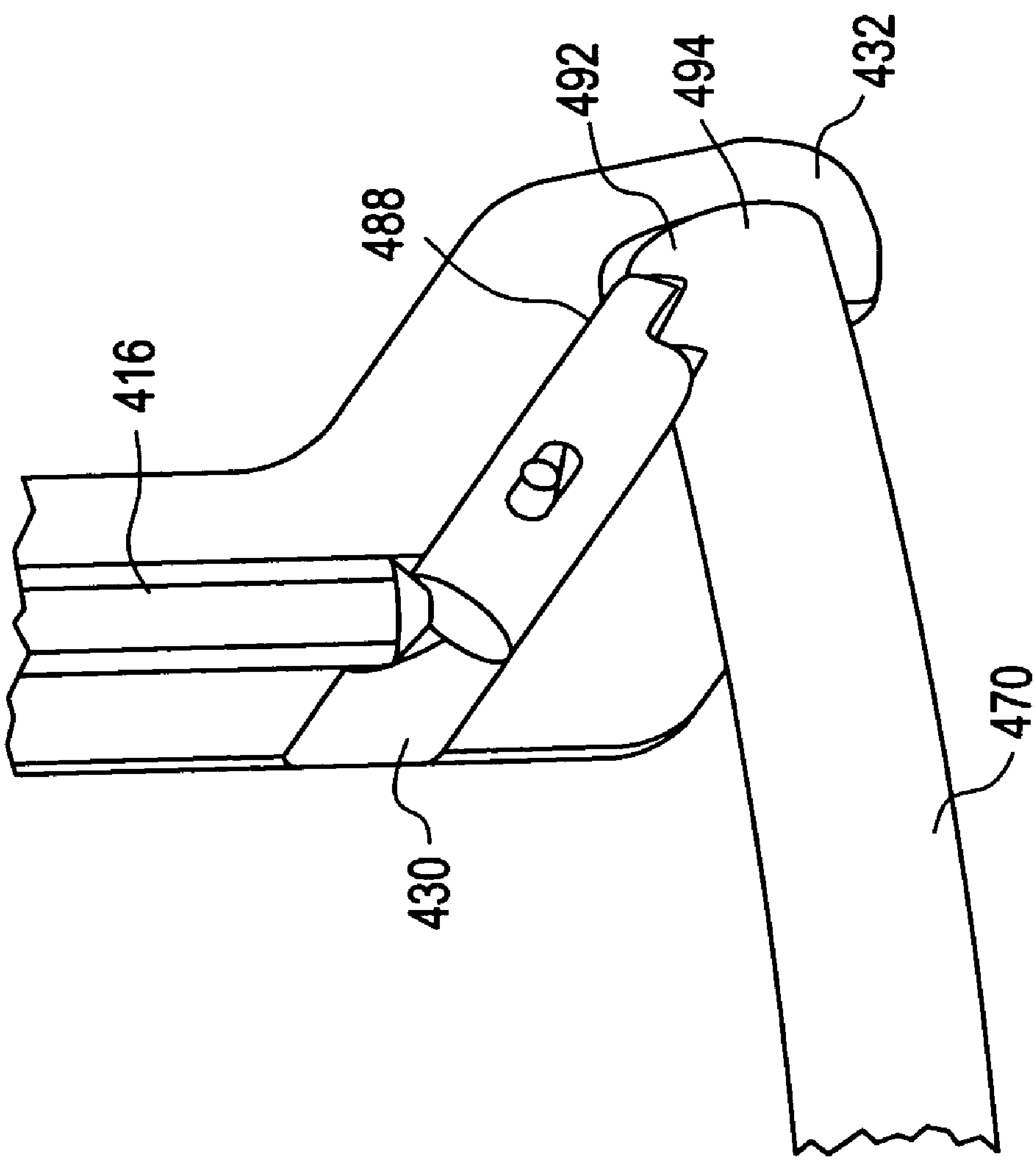


FIG. 38B

FIG. 38C

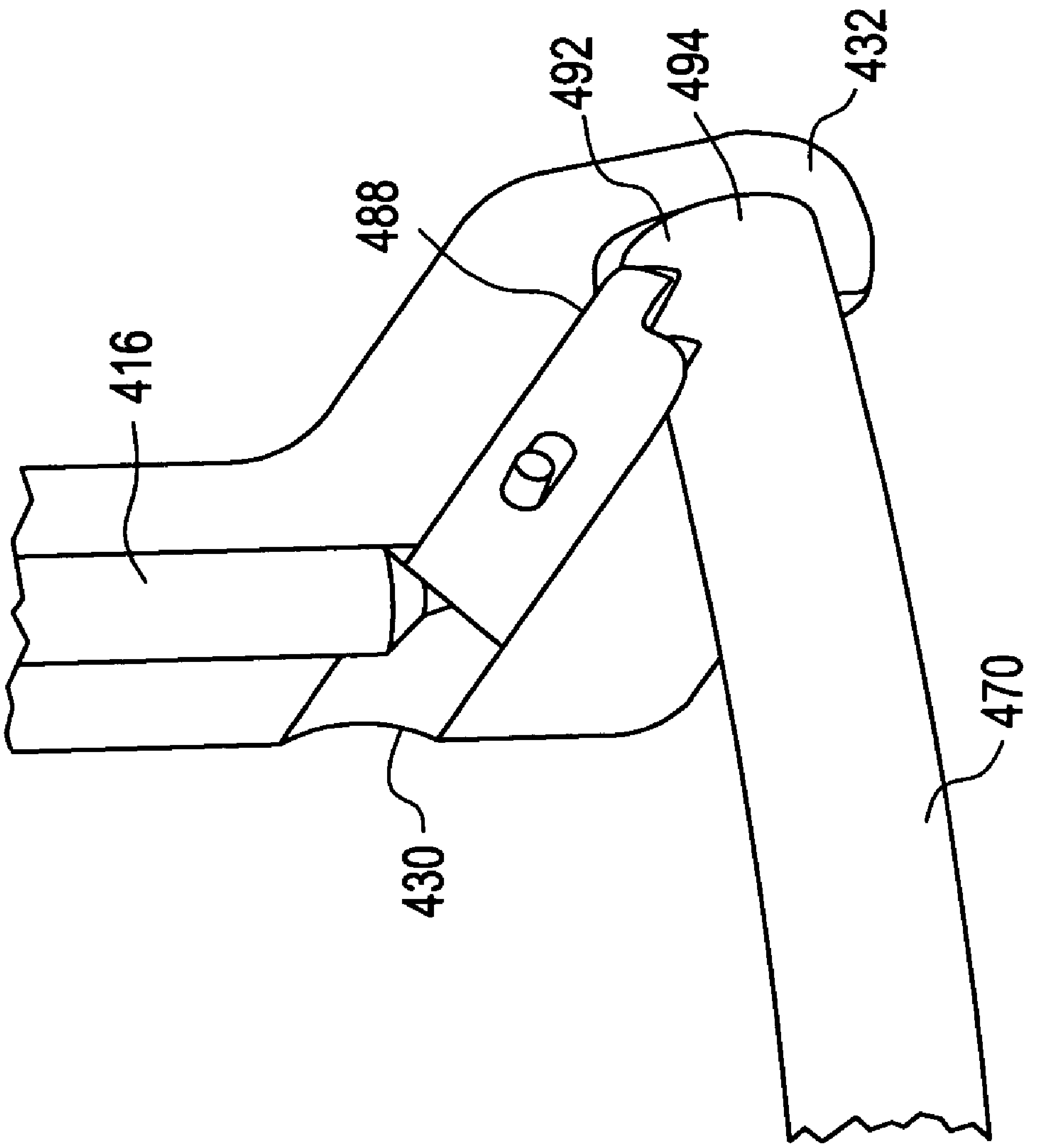


FIG. 38D

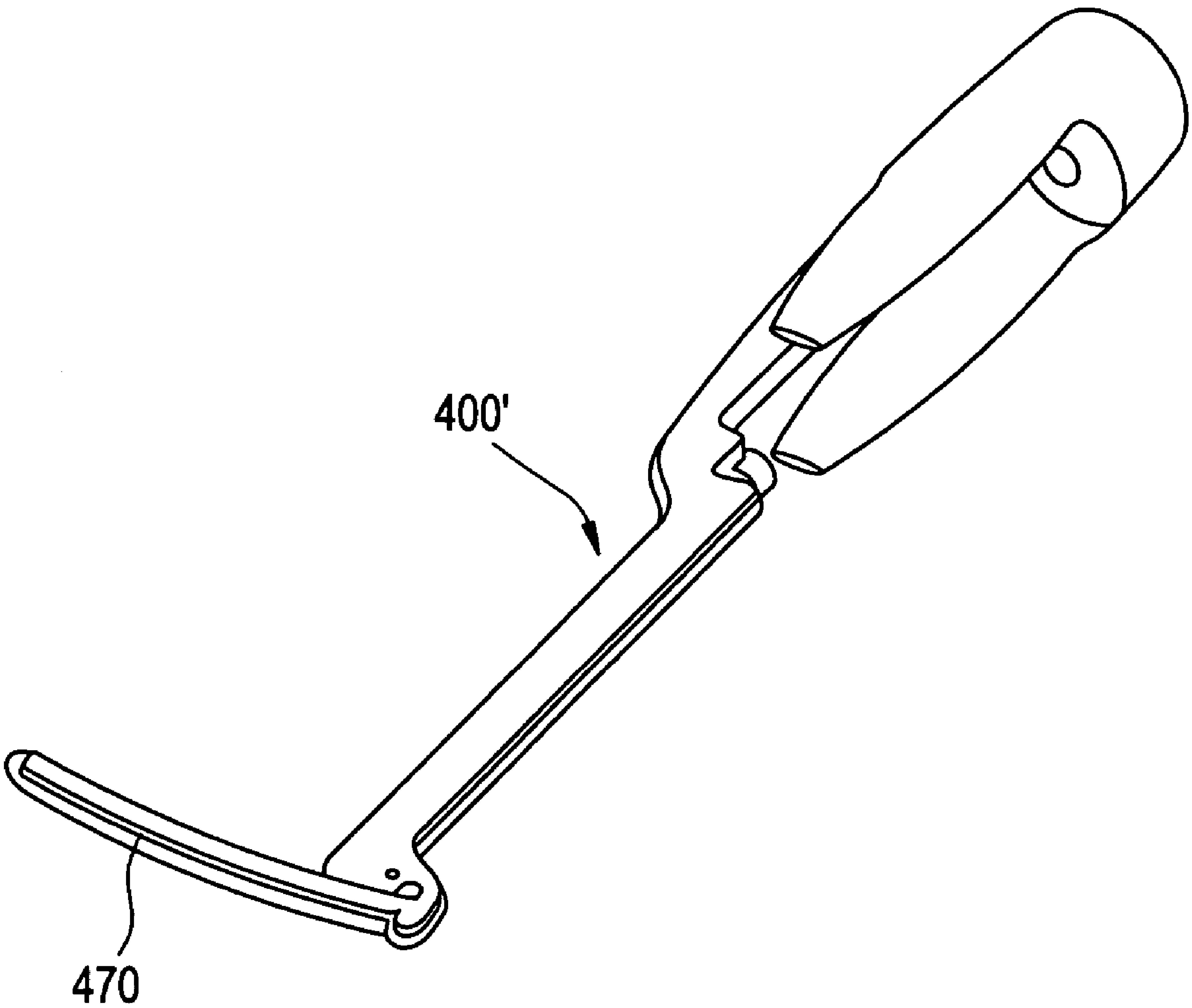


FIG. 39

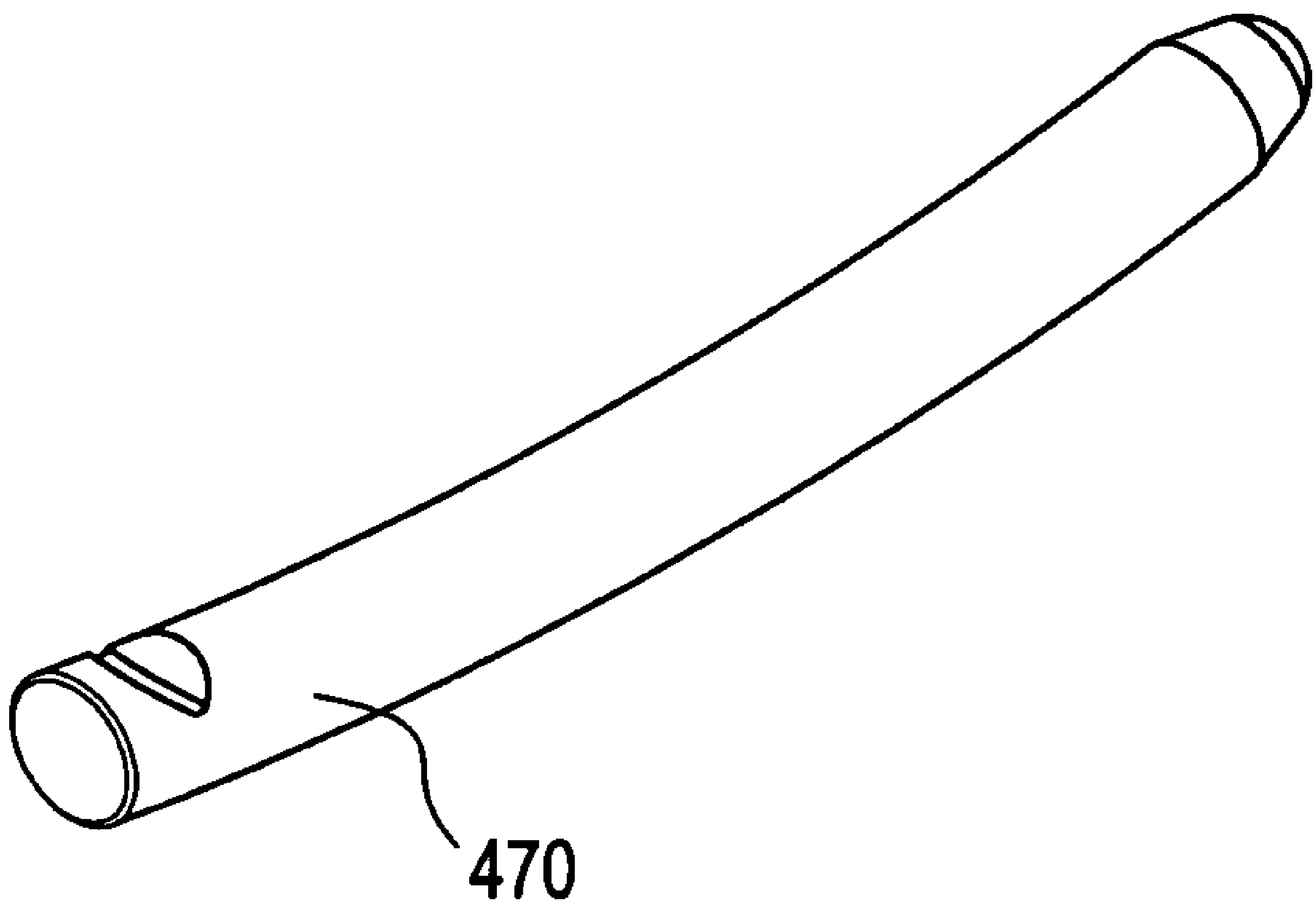


FIG. 40

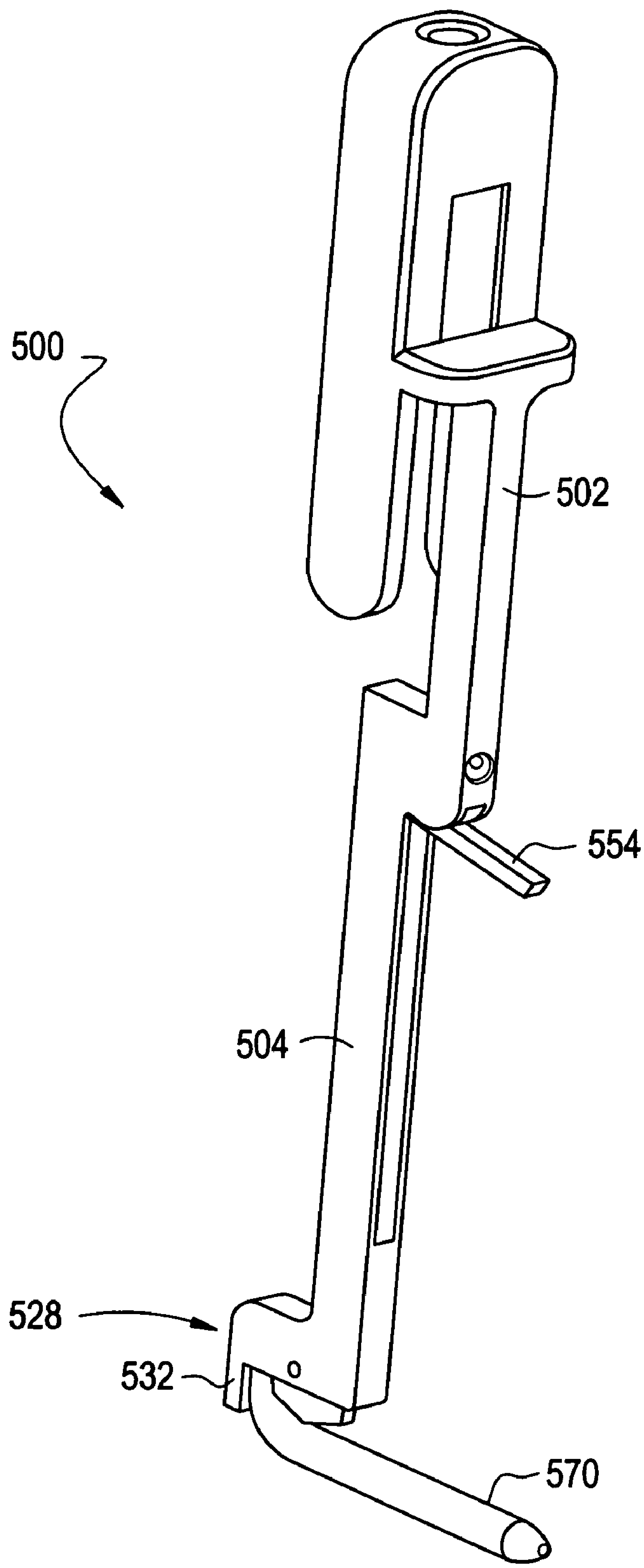


FIG. 41

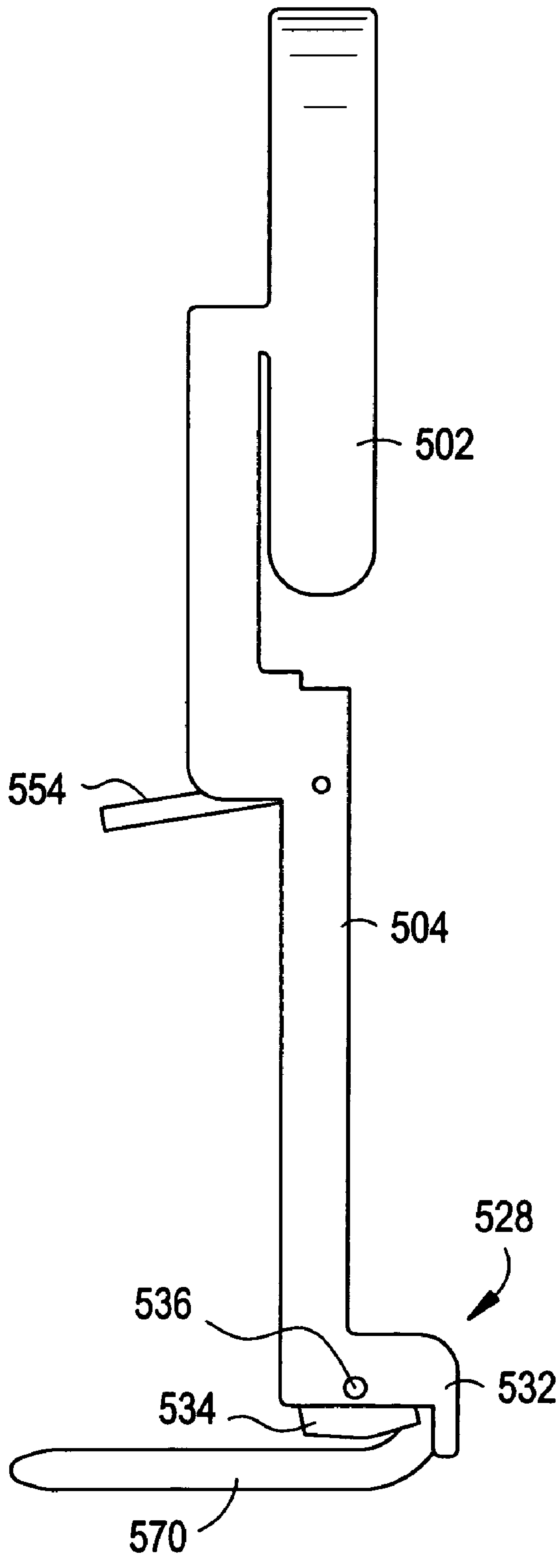


FIG. 42A

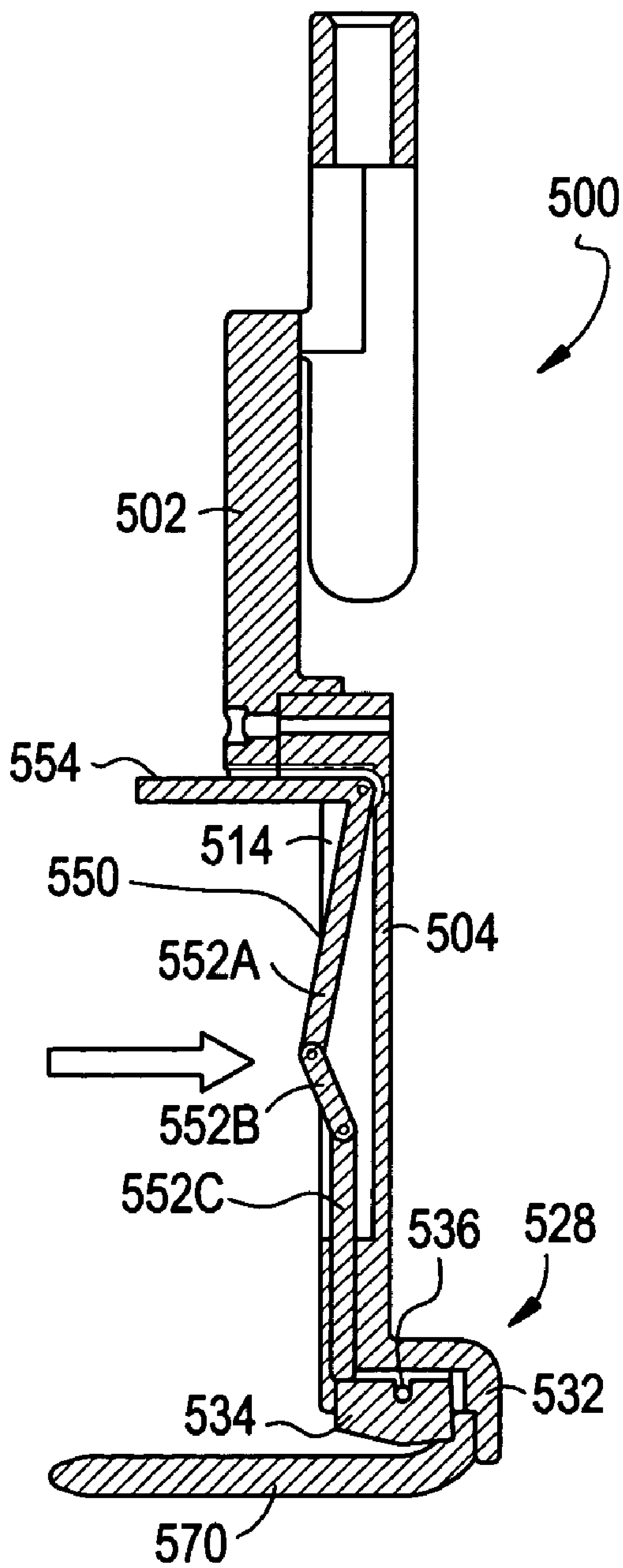


FIG. 42B

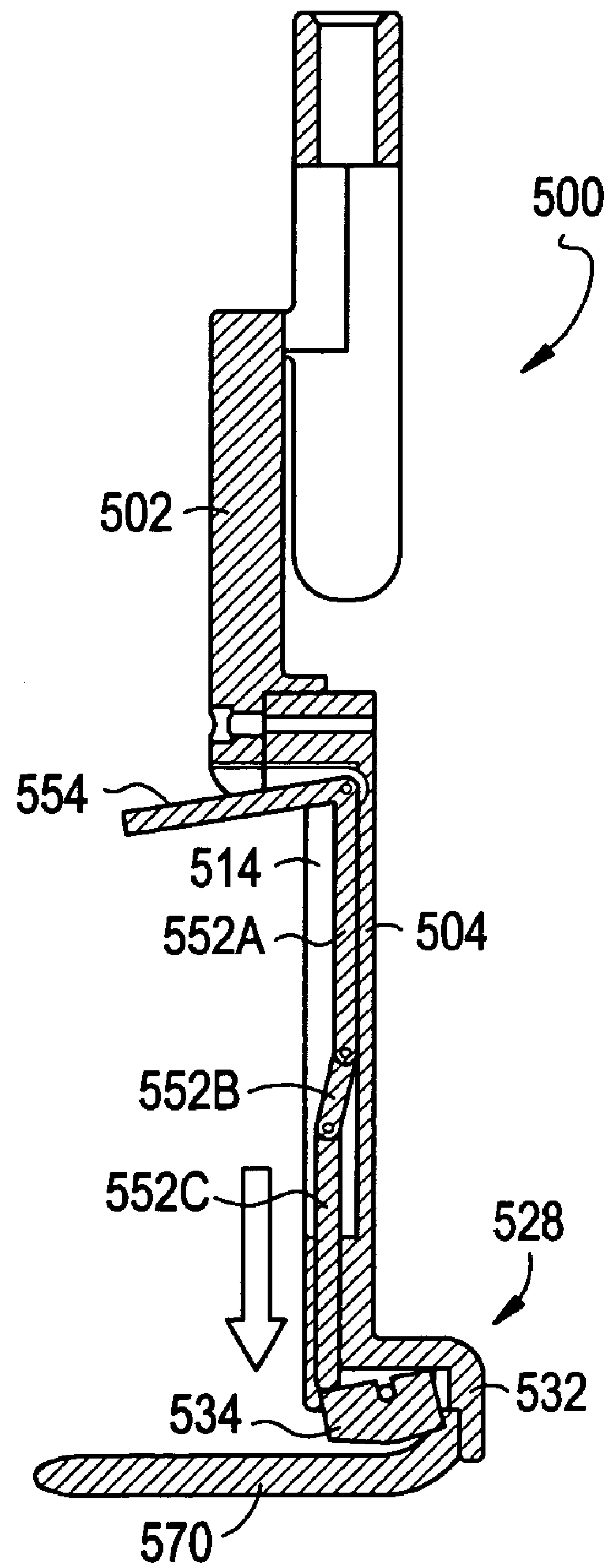


FIG. 43

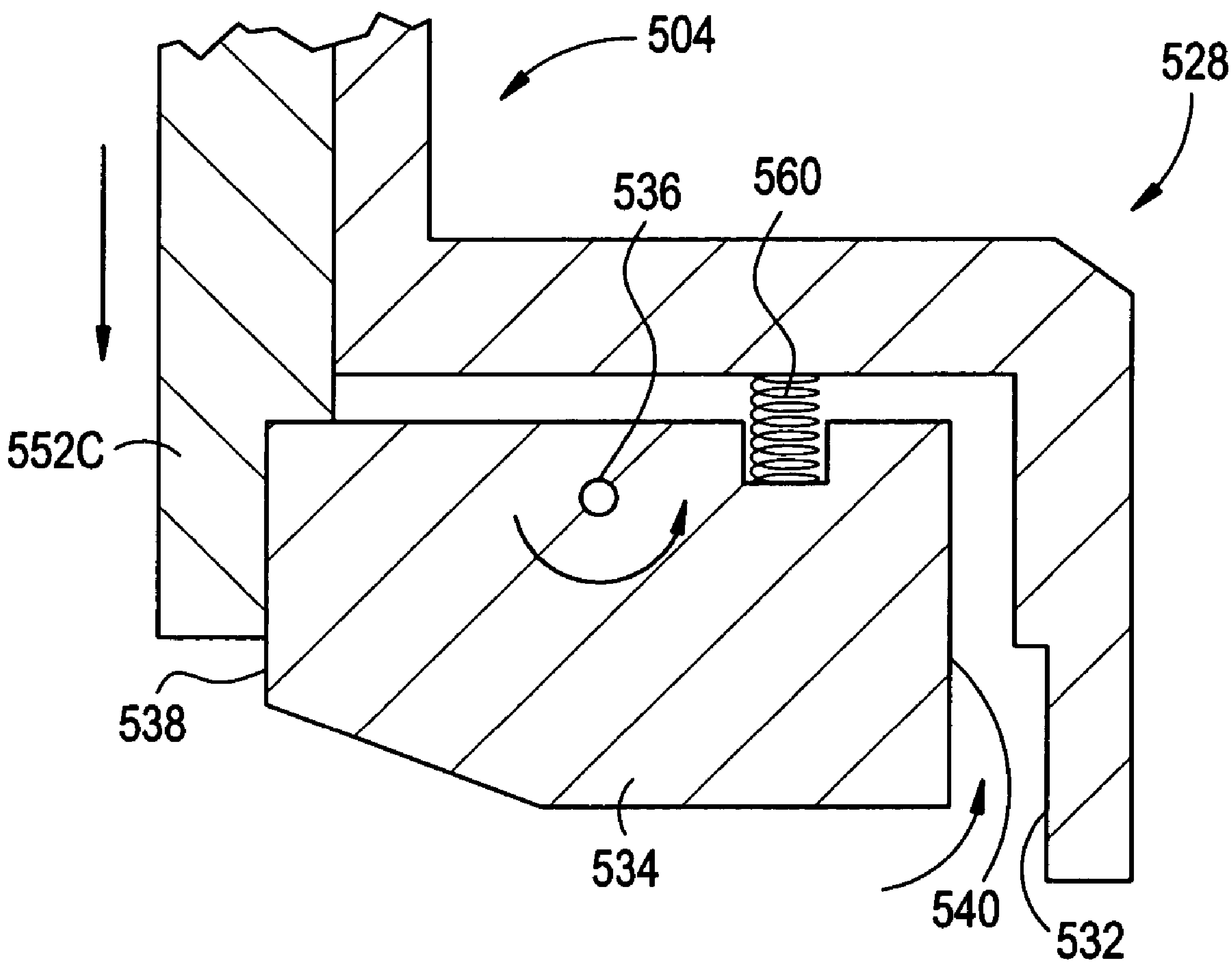


FIG. 44A

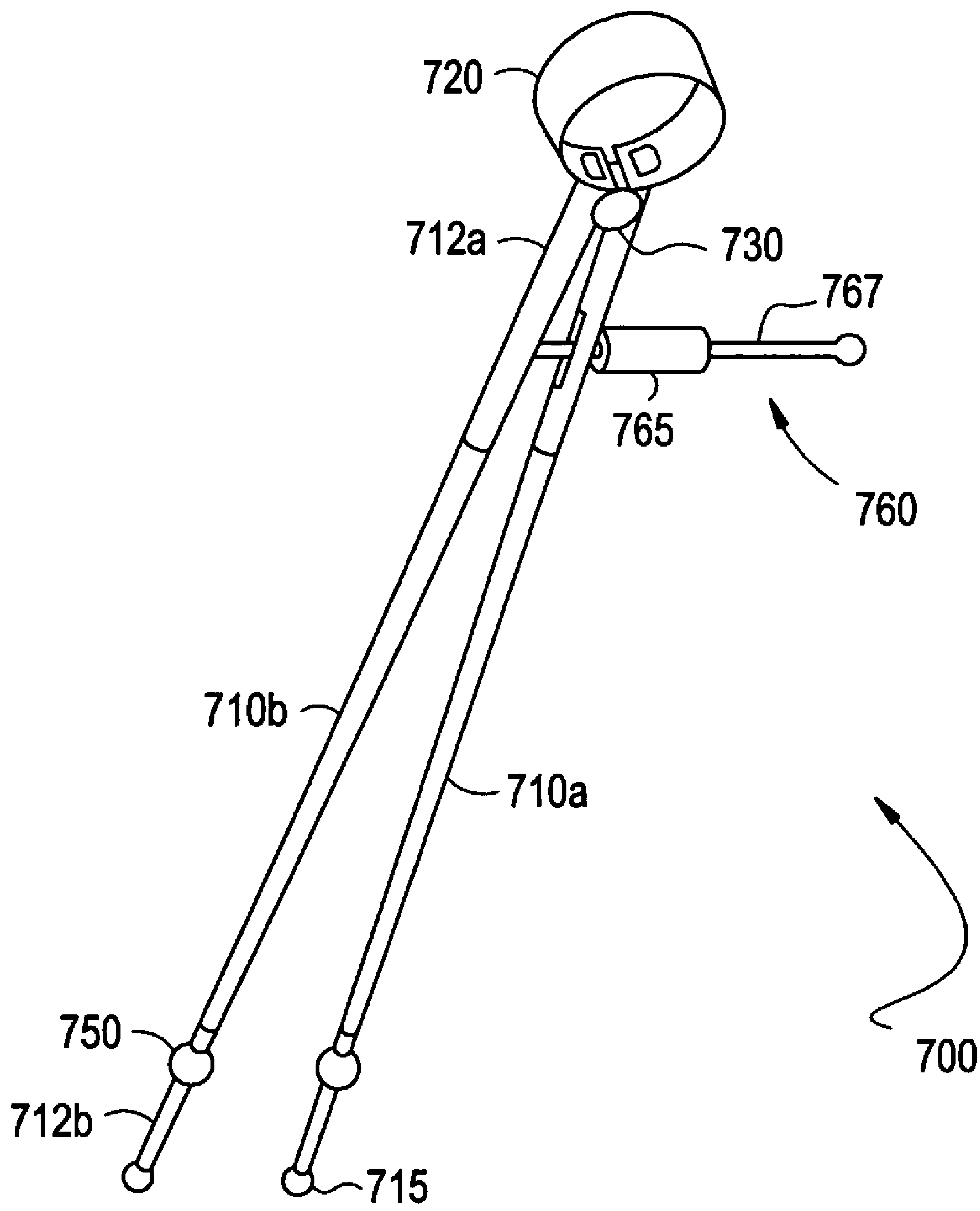


FIG. 44B

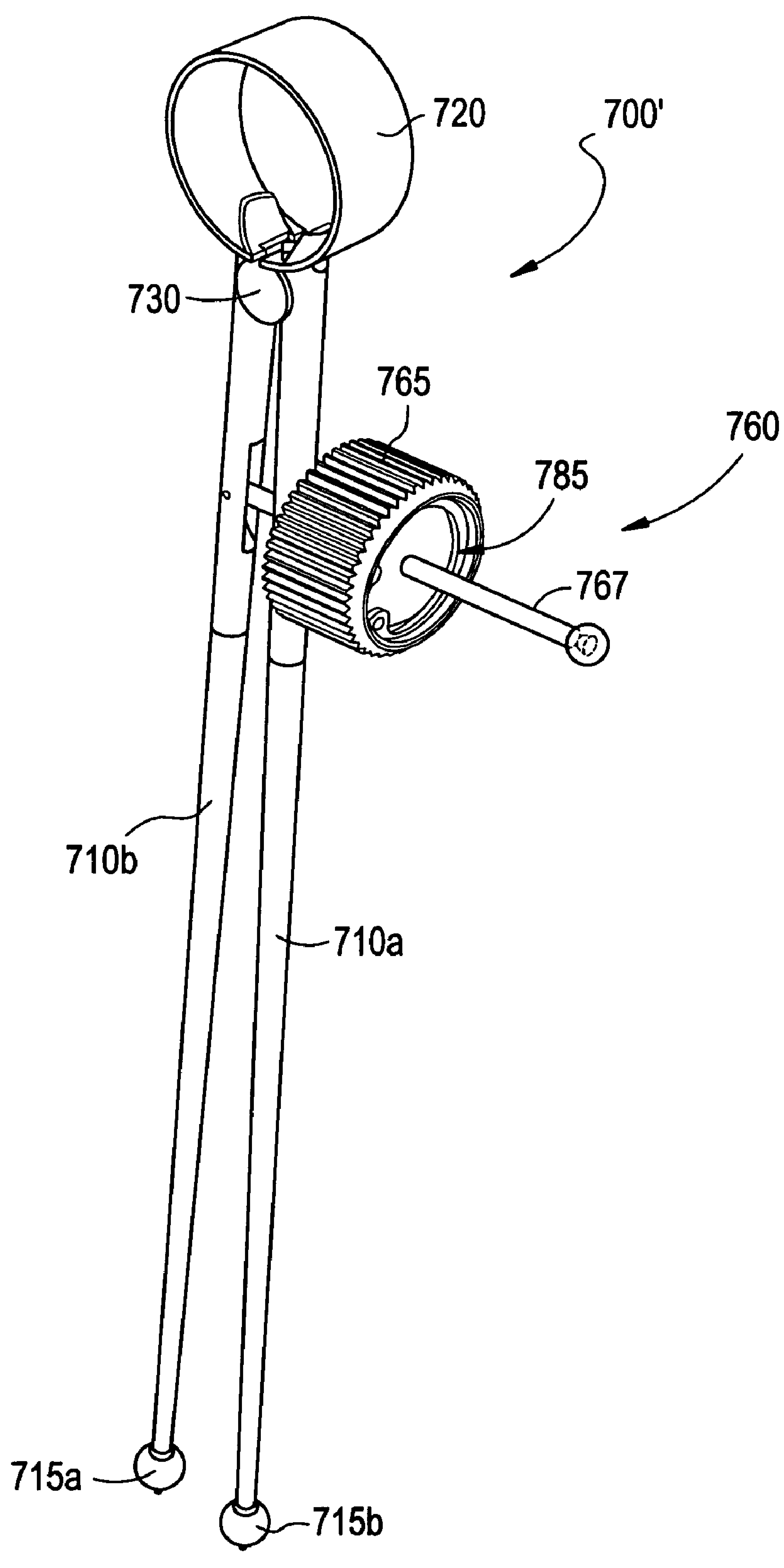


FIG. 45

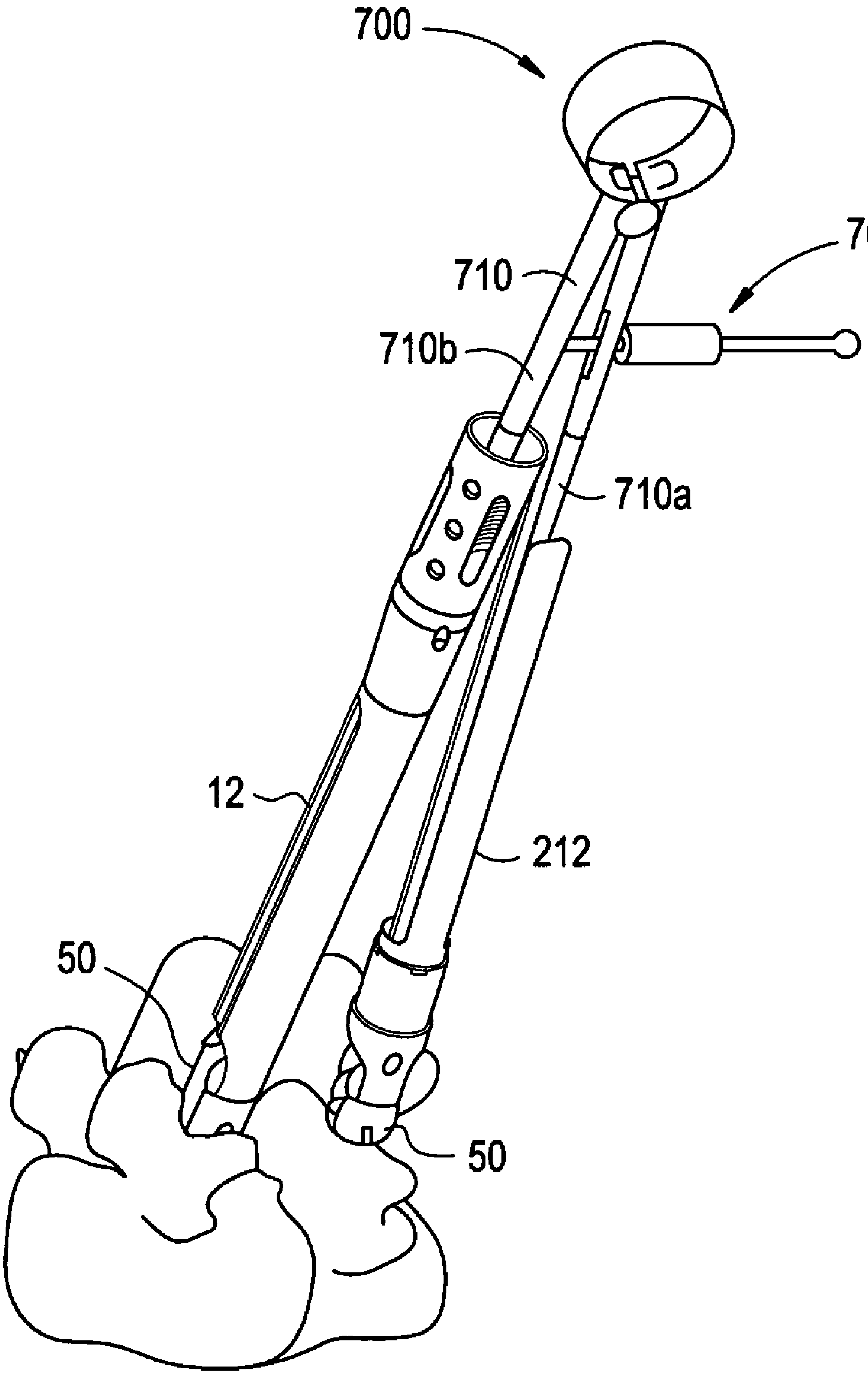


FIG. 46

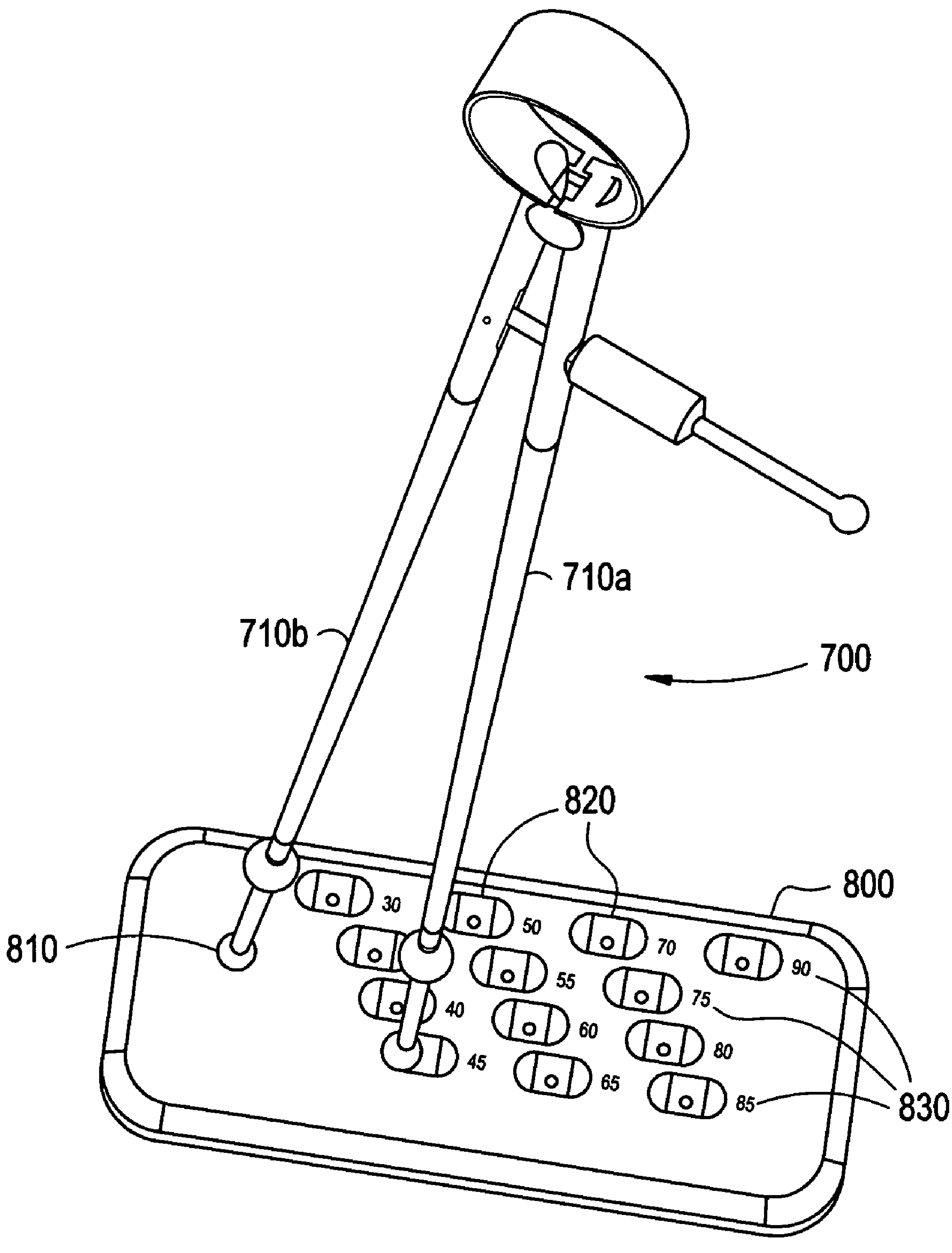


FIG. 47A

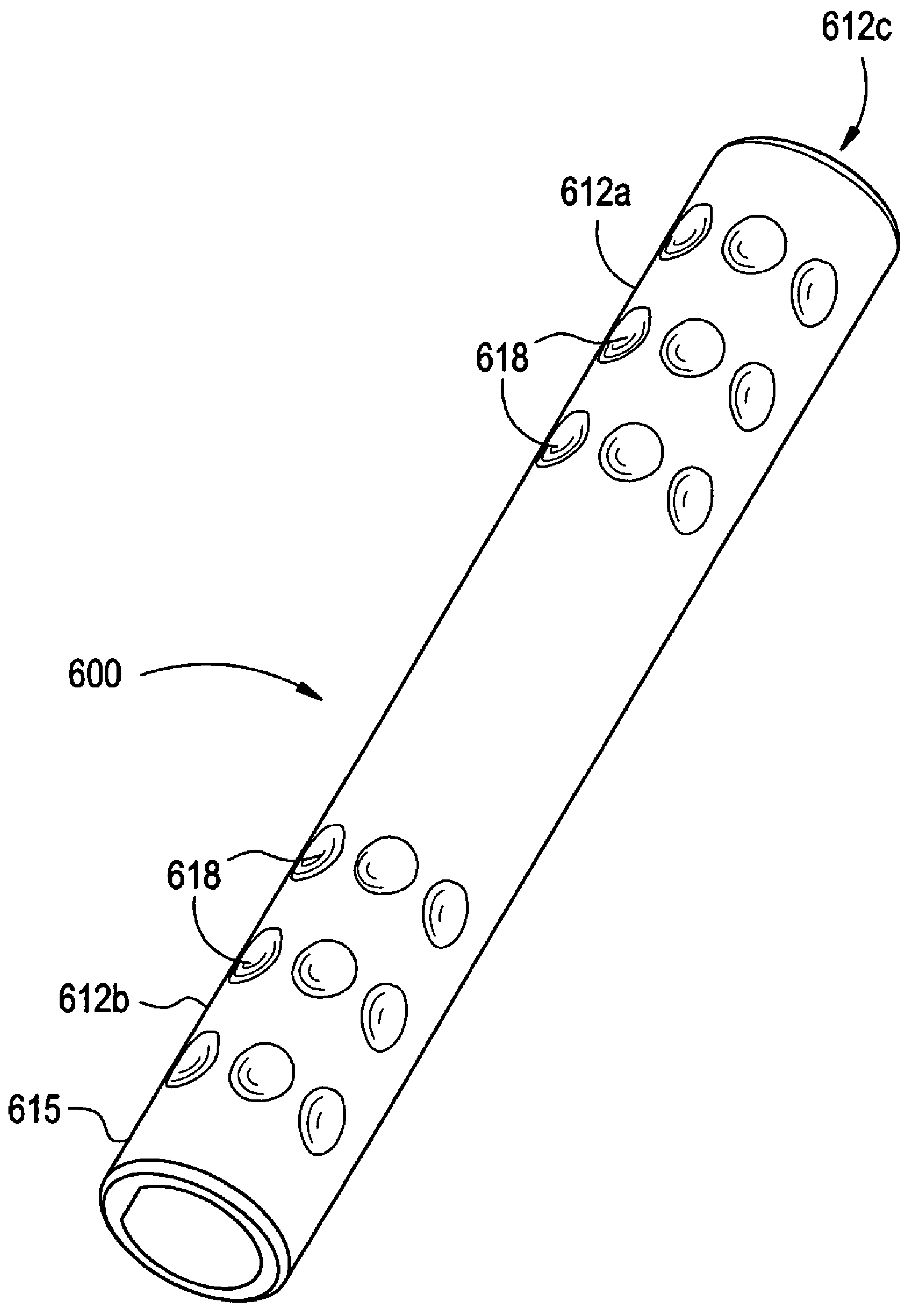


FIG. 47B

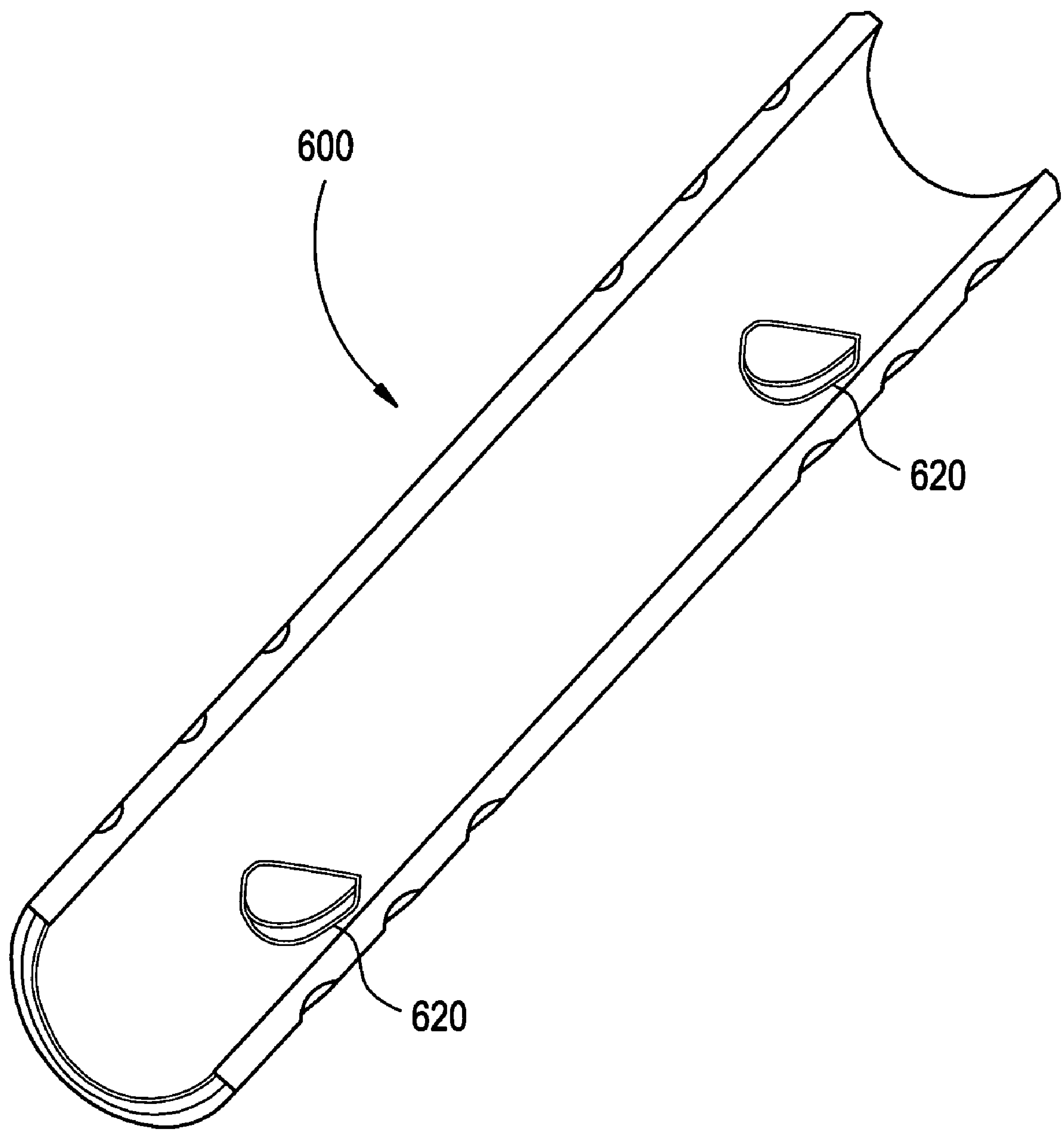


FIG. 47C

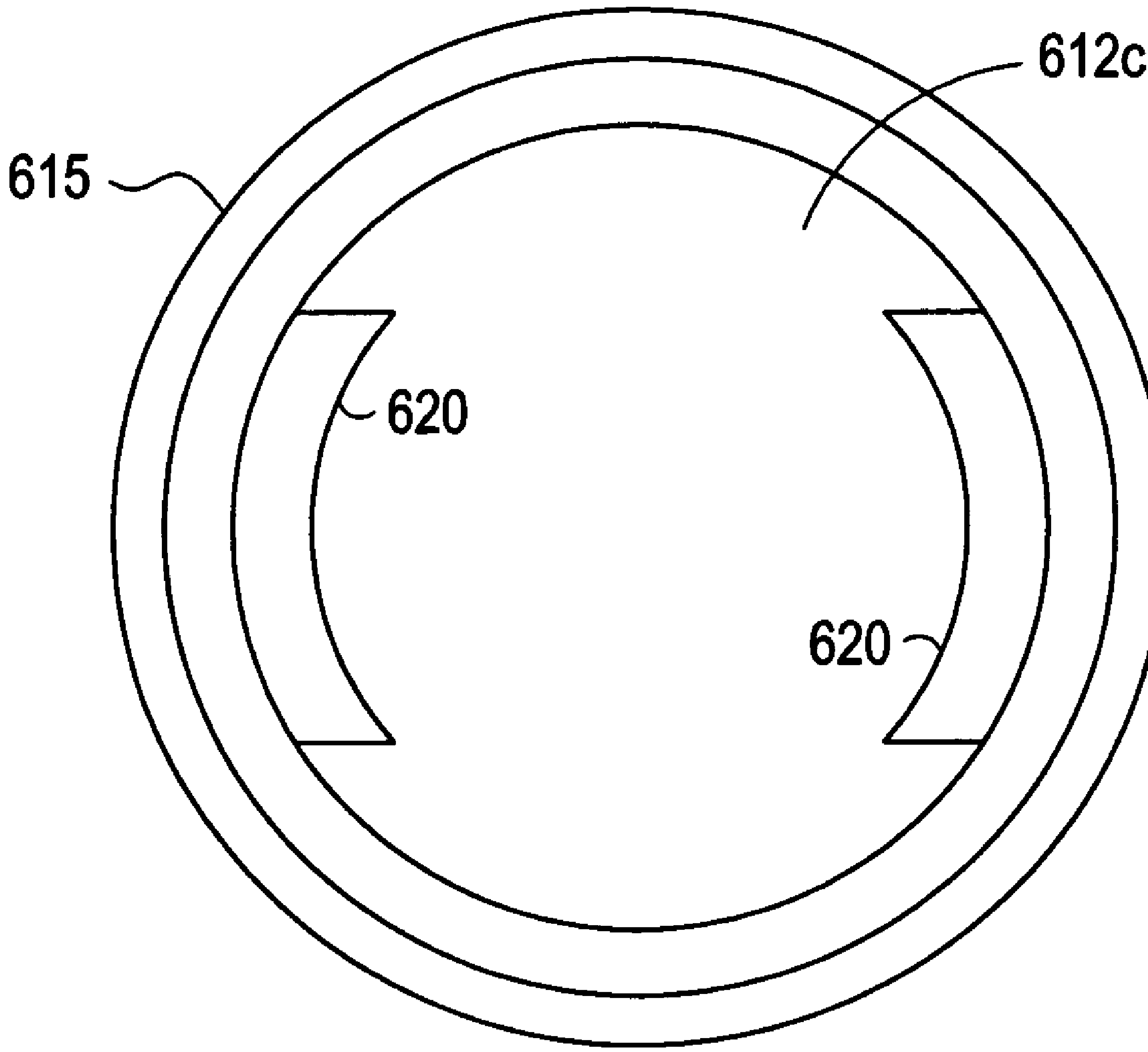
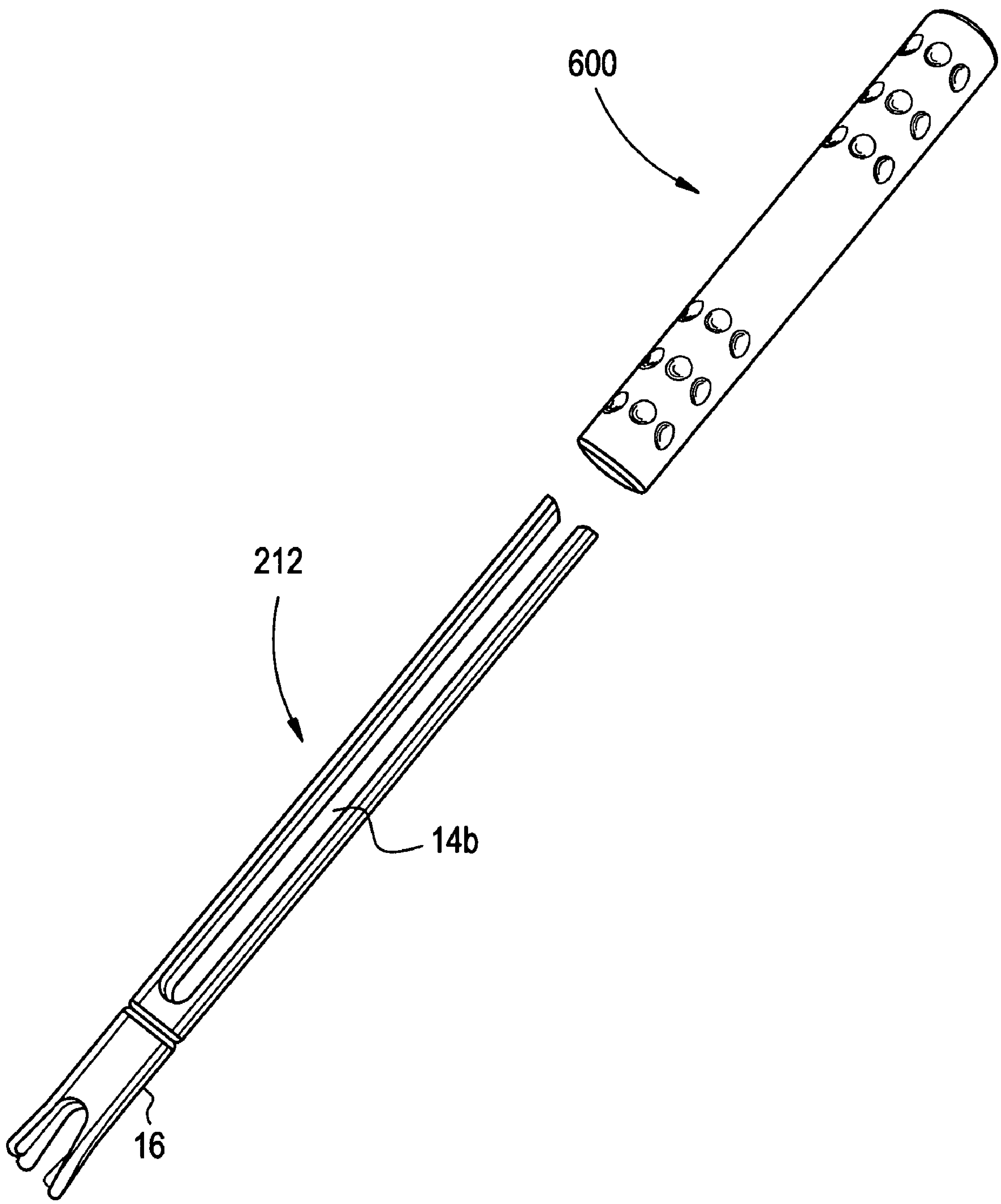


FIG. 48



DEVICES AND METHODS FOR INSERTING A SPINAL FIXATION ELEMENT

CROSS-REFERENCE TO RELATED APPLICATIONS

This application claims priority to U.S. Provisional Patent Application No. 60/542,548, filed Feb. 6, 2004, and U.S. Provisional Patent Application No. 60/565,784, filed Apr. 27, 2004, both of which are incorporated herein by reference.

BACKGROUND

This application relates to tools for use in spinal surgery, and in particular to minimally invasive methods and devices for introducing a spinal fixation element to one or more spinal anchor sites within a patient's spine.

For a number of known reasons, spinal fixation devices are used in orthopedic surgery to align and/or fix a desired relationship between adjacent vertebral bodies. Such devices typically include a spinal fixation element, such as a relatively rigid fixation rod, that is coupled to adjacent vertebrae by attaching the element to various anchoring devices, such as hooks, bolts, wires, or screws. The fixation elements can have a predetermined contour that has been designed according to the properties of the target implantation site, and once installed, the instrument holds the vertebrae in a desired spatial relationship, either until desired healing or spinal fusion has taken place, or for some longer period of time.

Spinal fixation elements can be anchored to specific portions of the vertebrae. Since each vertebra varies in shape and size, a variety of anchoring devices have been developed to facilitate engagement of a particular portion of the bone. Pedicle screw assemblies, for example, have a shape and size that is configured to engage pedicle bone. Such screws typically include a threaded shank that is adapted to be threaded into a vertebra, and a head portion having a rod-receiving element, usually in the form of a U-shaped slot formed in the head. A set-screw, plug, or similar type of fastening mechanism is used to lock the fixation element, e.g., a spinal rod, into the rod-receiving head of the pedicle screw. In use, the shank portion of each screw is threaded into a vertebra, and once properly positioned, a rod is seated through the rod-receiving member of each screw and the rod is locked in place by tightening a cap or other fastener mechanism to securely interconnect each screw and the fixation rod.

Recently, the trend in spinal surgery has been moving toward providing minimally invasive devices and methods for implanting spinal fixation devices. One such method, for example, is disclosed in U.S. Pat. No. 6,530,929 of Justis et al. and it utilizes two percutaneous access devices for implanting an anchoring device, such as a spinal screw, into adjacent vertebrae. A spinal rod is then introduced through a third incision a distance apart from the percutaneous access sites, and the rod is transversely moved into the rod-engaging portion of each spinal screw. The percutaneous access devices can then be used to apply closure mechanisms to the rod-engaging heads to lock the rod therein. While this procedure offers advantages over prior art invasive techniques, the transverse introduction of the rod can cause significant damage to surrounding tissue and muscle. Moreover, the use of three separate access sites can undesirably lengthen the surgical procedure, and increase patient trauma and recovery time.

Accordingly, there remains a need for improved minimally invasive devices and methods for introducing a spinal fixation element into a patient's spine.

SUMMARY

Disclosed herein are minimally invasive methods and devices for delivering a spinal fixation element to one or more spinal anchor sites in a patient's spinal column. In one exemplary embodiment, a method for introducing a spinal fixation element into a patient's spinal column may comprise providing at least two percutaneous access devices, engaging a spinal fixation element to a shaft of a manipulator instrument, positioning the shaft of the manipulator instrument through the at least one sidewall opening of the at least two percutaneous access devices such that the spinal fixation element extends in an orientation substantially parallel to the longitudinal axis of each percutaneous access device, and rotating the manipulator instrument to change the orientation of the spinal fixation element to a substantially transverse orientation to seat the spinal fixation element in the receiver head of at least two adjacent spinal anchors.

In another exemplary embodiment, a percutaneous access system for introducing a spinal fixation element into a patient's body may comprise a plurality of spinal anchors that are adapted to be implanted in bone, a plurality of elongate, generally cylindrical hollow tubes, a manipulator instrument adapted to engage a spinal fixation element, and a spinal fixation element that is adapted to be engaged by the manipulator instrument and positioned in relation to at least two spinal anchors disposed within adjacent vertebra. In the exemplary embodiment, the tubes may have a proximal end, a distal end that is adapted to mate to a spinal anchor, and at least one sidewall opening extending from the distal end of the hollow tube and terminating at a position distal to the proximal end.

In a further exemplary embodiment, an instrument for positioning a spinal rod through a lumen of a cannula may comprise a shaft having a proximal end, a distal end and a longitudinal axis extending therebetween, and a rod engaging mechanism disposed at the distal end of the shaft. In the exemplary embodiment, the shaft may have an extent in a direction transverse to the longitudinal axis that is less than an extent of the lumen of the cannula and the rod engaging mechanism may have a rod engaging surface. The rod engaging mechanism, in the exemplary embodiment, may be movable between a first position, in which the rod engaging surface engages the rod, and a second position, in which the rod engaging surface is displaced from the rod.

In another exemplary embodiment, a method for determining the length of a spinal fixation element for insertion between two bone anchors may comprise inserting a first arm of a measuring instrument through a first percutaneous access device into proximity to a first bone anchor connected to the first percutaneous access device, inserting a second arm of the measuring instrument through a second percutaneous access device into proximity to a second bone anchor connected to the second percutaneous access device, determining the distance between a distal end of the first arm and distal end of a second arm, and selecting a spinal fixation element based on the determined distance.

In a further exemplary embodiment, a method for introducing a spinal fixation element between two bone anchors may comprise engaging a spinal fixation element to a shaft of an instrument, positioning the shaft of the instrument through a sidewall opening of a first percutaneous access device connected to a first bone anchor and through a side wall opening of a second percutaneous access device connected to a second bone anchor, the spinal fixation element extending in an orientation substantially parallel to the longitudinal axis of at least one of the first percutaneous access device and the

second percutaneous access device, and pivoting the instrument to change the orientation of the spinal fixation element and position the spinal fixation element in proximity to the first bone anchor and in proximity to the second bone anchor.

BRIEF DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the methods and devices disclosed herein will be more fully understood by reference to the following detailed description in conjunction with the attached drawings in which like reference numerals refer to like elements through the different views. The drawings illustrate principles of the methods and devices disclosed herein and, although not to scale, show relative dimensions.

FIG. **1** is a perspective view of an exemplary embodiment of a percutaneous access device coupled to a spinal anchor;

FIG. **2** is a side elevational view taken along the longitudinal axis L of the percutaneous access device shown in FIG. **1**;

FIG. **3** is a side view of an exemplary embodiment of a percutaneous access device;

FIG. **4** is a perspective view of an exemplary embodiment of a percutaneous access device;

FIGS. **5**A and B are cutaway perspective views of an exemplary embodiment of a percutaneous access device having a guide member;

FIG. **6**A is a sideview of an exemplary embodiment of a percutaneous access device having an external guide member;

FIG. **6**B is cutaway view showing a spinal fixation element moving through the percutaneous access device of FIG. **6**A;

FIG. **7**A is front view of an exemplary embodiment of an instrument for engaging a spinal fixation element;

FIG. **7**B is a side view of the instrument of FIG. **7**A;

FIG. **7**C is an bottom view of the instrument of FIG. **7**C;

FIG. **8**A is a front view of the instrument of FIG. **7**A, illustrating a spinal fixation element connected to a distal end of the instrument;

FIG. **8**B is a side view of the instrument of FIG. **7**A, illustrating a spinal fixation element connected to a distal end of the instrument;

FIG. **8**C is a bottom view of the instrument of FIG. **7**A, illustrating a spinal fixation element connected to a distal end of the instrument;

FIG. **8**D is a perspective view of the distal end of the instrument of FIG. **7**A, illustrating the connection of a spinal fixation element to the instrument;

FIG. **9**A is a perspective view of a distal end of an instrument for engaging a spinal fixation element, the exemplary instrument having a clamping mechanism with a clamp jaw;

FIG. **9**B is a perspective view of the instrument of FIG. **9**A, illustrating the instrument connected to a spinal fixation element;

FIG. **10**A is a perspective view of an instrument for engaging a spinal fixation element, the exemplary instrument having a collet designed to engage a spinal fixation element;

FIG. **10**B is a perspective view of the collet of the instrument of FIG. **10**A;

FIG. **10**C is a perspective view of the collet of the instrument of FIG. **10**A, illustrating the collet engaging a spinal fixation element;

FIG. **11**A is a perspective view of the distal end of another exemplary embodiment of an instrument for engaging a spinal fixation element, illustrating the instrument connected to a spinal rod;

FIG. **11**B is a perspective view of the distal end of the instrument of FIG. **11**A, illustrating the instrument engaged to a spinal fixation element;

FIG. **11**C is a partially cut away, perspective view of the distal end of the instrument of FIG. **11**A, illustrating the instrument disengaged from a spinal fixation element;

FIGS. **12-17** illustrate a method of inserting a spinal fixation element through the percutaneous access devices shown in FIGS. **1-4**;

FIGS. **18-19** illustrate an instrument for determining the position of a spinal fixation element relative to a spinal anchor;

FIGS. **20-25** illustrate a method of inserting a spinal fixation element through the percutaneous access devices shown in FIG. **4**;

FIGS. **26-28** illustrate a method of inserting a spinal fixation element through the percutaneous access devices shown in FIGS. **6**A-**6**B;

FIGS. **29-31** illustrate another exemplary embodiment of an instrument for engaging a spinal fixation element, the exemplary instrument engaging the spinal fixation element to facilitate articulation of the spinal fixation element;

FIG. **32**A is a perspective view of another exemplary embodiment of an instrument for engaging a spinal fixation element, illustrating the instrument connected to a spinal rod;

FIG. **32**B is an exploded perspective view of the instrument of FIG. **32**A;

FIG. **32**C is a rear elevation view of the instrument of FIG. **32**A;

FIG. **33**A is a front perspective view of the handle of the instrument of FIG. **32**A;

FIG. **33**B is a rear perspective view of the handle of the instrument of FIG. **32**A;

FIG. **33**C is a side elevational view of the handle of the instrument of FIG. **32**A;

FIG. **34**A is a perspective view of the shaft of the instrument of FIG. **32**A;

FIG. **34**B is a side elevation view in cross section of the shaft of the instrument of FIG. **32**A;

FIG. **35**A is a side elevational view of the elongated pin of the instrument of FIG. **32**A;

FIG. **35**B is a side elevational view in cross section of the proximal end of the elongated pin of the instrument of FIG. **32**A;

FIG. **36** is a perspective view of the rod engagement mechanism of the instrument of FIG. **32**A;

FIG. **37** is a side elevational view in cross section of the shaft of the instrument of FIG. **32**A, illustrating the operation of the instrument;

FIG. **38**A is a side elevational view in cross section of the distal end of the shaft of the instrument of FIG. **32**A, illustrating the operation of the instrument;

FIGS. **38**B and **38**C are a side elevational views in cross section of an alternate embodiment of a distal end of the shaft of the instrument of FIG. **32**A, illustrating the instrument connected to a spinal fixation element;

FIG. **38**D is a perspective view of an instrument having the distal end illustrated in FIGS. **38**B and **38**C;

FIG. **39** is a perspective view of an exemplary embodiment of a spinal fixation element;

FIG. **40** is a perspective view of another exemplary embodiment of an instrument for engaging a spinal fixation element, illustrating the instrument connected to a spinal fixation element;

FIG. **41** is a side elevational view of the instrument of FIG. **40**;

FIG. 42A is a side elevational view in cross section of the instrument of FIG. 40, illustrating the instrument in a first, disengaged position;

FIG. 42B is a side elevational view in cross section of the instrument of FIG. 40, illustrating the instrument in a second, engaged position;

FIG. 43 is a side elevational view in cross section of the distal end instrument of FIG. 40, illustrating operation of the rod engaging mechanism of the instrument;

FIGS. 44A and 44B are perspective views of exemplary embodiments of an instrument for determining the distance between two bone anchors;

FIG. 45 is a perspective view of the instrument of FIG. 44A, illustrating the instrument inserted through two percutaneous access devices;

FIG. 46 is a perspective view of the instrument of FIG. 44A, illustrating the instrument positioned within a template block;

FIG. 47A is a perspective view of an exemplary embodiment of a sleeve for use with a percutaneous access device to facilitate manipulation of the percutaneous access device;

FIG. 47B is a cut away view of the sleeve of FIG. 47A;

FIG. 47C is an end view of the sleeve of FIG. 47A; and

FIG. 48 is a perspective view of the sleeve of FIG. 47A, illustrating the sleeve being positioned over a percutaneous access device.

DETAILED DESCRIPTION

Certain exemplary embodiments will now be described to provide an overall understanding of the principles of the structure, function, manufacture, and use of the devices and methods disclosed herein. One or more examples of these embodiments are illustrated in the accompanying drawings. Those of ordinary skill in the art will understand that the devices and methods specifically described herein and illustrated in the accompanying drawings are non-limiting exemplary embodiments and that the scope of the present invention is defined solely by the claims. The features illustrated or described in connection with one exemplary embodiment may be combined with the features of other embodiments. Such modifications and variations are intended to be included within the scope of the present invention.

The articles "a" and "an" are used herein to refer to one or to more than one (i.e. to at least one) of the grammatical object of the article. By way of example, "an element" means one element or more than one element.

The terms "comprise," "include," and "have," and the derivatives thereof, are used herein interchangeably as comprehensive, open-ended terms. For example, use of "comprising," "including," or "having" means that whatever element is comprised, had, or included, is not the only element encompassed by the subject of the clause that contains the verb.

Disclosed herein are minimally invasive methods and devices for introducing a spinal fixation element into a surgical site in a patient's spinal column. In general, the methods disclosed herein involve advancing a spinal fixation element in a lengthwise orientation along a minimally invasive pathway that extends from a minimally invasive percutaneous incision to a spinal anchor site. In one exemplary embodiment, a percutaneous access device is used to create the minimally invasive pathway for receiving the spinal fixation element and for delivering the fixation element to a spinal anchor site. The spinal fixation element is preferably inserted through a lumen in the percutaneous access device in a lengthwise orientation, such that the spinal fixation element is oriented substantially parallel to a longitudinal axis of the percutaneous access device. As the spinal fixation element approaches or reaches the distal end of the pathway, the spinal fixation element can be manipulated to orient it at a desired angle with respect to the percutaneous access device, preferably such that the spinal fixation element is substantially parallel to the patient's spinal column. The spinal fixation element can then optionally be positioned to couple the spinal fixation element, either directly or indirectly, to one or more spinal anchors. A fastening element or other closure mechanism, if necessary, can then be introduced into the spinal anchor site to fixedly mate the spinal fixation element to the anchor(s).

The methods and devices disclosed herein are particularly advantageous in that they can be achieved using one or more minimally invasive percutaneous incisions for accessing the spinal column. Such incisions minimize damage to intervening tissues, and reduce recovery time and post-operative pain. The methods and devices disclosed herein may advantageously provide techniques for delivering spinal fixation elements and anchors along a minimally invasive pathway, thus eliminating the need to create a large working area at the surgical site.

While a variety of devices can be used to perform the methods disclosed herein, FIGS. 1 and 2 illustrate an exemplary embodiment of a percutaneous access device 12 that is mated to a spinal anchor 50 (FIG. 1) to form a spinal implant assembly 10. As shown, the device 12 is in the form of a generally elongate, cylindrical tube having an inner lumen 12*c* formed therein and defining a longitudinal axis L that extends between proximal and distal ends 12*a*, 12*b*. The size of the access device 12 can vary depending on the intended use. In certain exemplary embodiments, for example, the percutaneous access device 12 may have a length l_a that allows the proximal end 12*a* of the access device 12 to be positioned outside the patient's body, while the distal end 12*b* of the access device 12 is coupled to, or positioned adjacent to, a spinal anchor, e.g., anchor 50, that is disposed in a vertebra in a patient's spine. The illustrated exemplary percutaneous access device 12 provides a minimally invasive pathway for the delivery of a spinal fixation element, such as a spinal rod. The exemplary percutaneous access device 12 may be implanted through a minimally invasive percutaneous incision, which is a relatively small incision that typically has a length that is less than a diameter or width of the device being inserted therethrough. For example, a minimally invasive percutaneous incision may be a stab or point incision through which the percutaneous access device is positioned.

In an exemplary embodiment, the device 12 has an inner diameter d_i that is sufficient to allow a spinal fixation element to be introduced therethrough, preferably in a lengthwise orientation. The inner diameter d_i can also optionally be configured to allow a driver mechanism to be introduced therethrough for applying a closure mechanism to lock the spinal fixation element in relation to a spinal anchor. The outer diameter d_o of the access device 12 can also vary, and it can be the same as, less than, or greater than an outer diameter d_r of the spinal anchor. In the illustrated embodiment, the access device 12 has an outer diameter d_o that is substantially the same as an outer diameter of the spinal anchor, which, in the illustrated exemplary embodiment, is the outer diameter of the receiver head or member 52 of the exemplary spinal screw 50. This is particularly advantageous in that the size of the incision does not need to be any larger than necessary. The matching outer diameters of the access device 12 and the anchor 50 also allow the access device 12 and/or the anchor 50 to be introduced through a cannula. If the access device 12 is mated to the anchor 50, the matching outer diameters also allow a sleeve or other device to be slidably disposed therearound to prevent disengagement between the access device **12** and the anchor **50**. In another, exemplary embodiment, the outer diameter d_o of the access device **12** can be slightly greater than the outer diameter of the spinal anchor. By way of non-limiting example, where a receiver head of the spinal anchor has an outer diameter that is about 13 mm, the access device **12** preferably has an outer diameter d_o that is about 15 mm.

The percutaneous access device **12** may also include a pair of opposed sidewall openings or slots **14***a* formed therein and extending proximally from the distal end **12***b* thereof. In an alternate exemplary embodiment of a percutaneous access device **212** shown in FIG. **3**, an additional pair of opposed proximal sidewall openings **14***b* are also formed in alignment with the first pair of distal sidewall openings **14***a* and extend distally from the proximal end **12***a* of the device. A web **16** is formed in the middle portion of the device separating the proximal and distal sidewall openings **14***a*, **14***b*. The sidewall openings **14***a,b* provide access to the lumen of the device **212** for an instrument holding a spinal fixation element and the spinal fixation element.

A spinal fixation element, such as, for example, a spinal rod, may be introduced through a sidewall opening, such as a proximal sidewall opening **14***b* of the embodiment illustrated in FIG. **3**, into the lumen of the device **212** in a first, lengthwise orientation, in which the spinal fixation element is substantially parallel to the longitudinal axis L of the access device **212**. The spinal fixation element can then to be manipulated to extend at an angle with respect to the first orientation, such that the fixation element extends in a direction substantially transverse to the longitudinal axis L of the access device **212**, for example, in a direction that is substantially parallel to the patient's spine. Since the length L of the spinal fixation element will necessarily be greater than the inner diameter d_i of the access device **212**, the openings **14** allow the spinal fixation element to pass therethrough while being transitioned from the first, lengthwise orientation to the second orientation. A person skilled in the art will appreciate that the exact position of the spinal fixation element with respect to the longitudinal axis L will of course vary depending on the configuration of the spinal fixation element.

As shown in FIGS. **3** and **4**, the shape and size of each sidewall opening **14***a,b* can vary, but the opening(s) **14***a,b* may be effective to allow movement of the spinal fixation element from the first orientation to the second orientation. The relationship of the length of the sidewall openings can vary. For example in the embodiment illustrated in FIG. **4**, each pair of sidewall openings **14***a,b* extend over about less than half of the length of the percutaneous access device **212**. In this exemplary embodiment, the device exhibits a generally H-shape when viewed facing the openings **14**. In the exemplary embodiment illustrated in FIG. **3**, the length of the proximal sidewall openings extends over more than half the length of the device and is longer than the length of the distal sidewall openings, however, one skilled in the art will appreciate that in other embodiments the length of the distal sidewall openings may be greater than the length of the proximal sidewall openings, depending for example, on the surgical approach, e.g., posterior, anterior, or lateral, and the region of the spine treated. In addition, the length l_p of the sidewall openings **14***b* at the proximal end of the device may depend on, for example, the size of the patient and the design of the instrument to hold the spinal fixation element.

The proximal sidewall openings **14***b* of the device, in the exemplary embodiment, are open at the proximal end **12***a* of the device. The proximal sidewall openings **14***b* terminate at the distal end thereof at the web **16**. Leaving the proximal sidewall openings **14***b* open at the proximal end **12***a* of the device allows for the instrument holding the spinal fixation element to pass through unobstructed as the instrument manipulates the spinal fixation element from one orientation to another orientation.

In the exemplary embodiment, the distal sidewall openings **14***a* in the distal end of the device may be open at the distal end **12***b*. The distal sidewall openings **14***a* terminate at the proximal end thereof at the web **16**. The web **16**, in the exemplary embodiment, provides strength and rigidity to the device **212** and provides a bearing surface to facilitate manipulation of the spinal fixation element with an instrument, as discussed below. The length l_d of the distal sidewall openings **14***a* can be, for example, a function of the distance between the spinal anchors, the length of the spinal fixation element, the surgical approach, the region of the spine being treated, and/or the patient anatomy. The length of the sidewall openings **14***a*, **14***b* may determine the placement of the web **16**, which can be used as a guide to facilitate rotation of the instrument holding the spinal fixation element when manipulating the fixation element from one orientation to a second orientation. The shape of the sidewall openings **14***a, b* can be generally elongate, and may have a width w that is sufficient to accommodate the diameter of the spinal fixation element and the shaft of the instrument holding the spinal fixation element. Another function of the length of the access device is to enable the shaft of the manipulator instrument to maintain contact with the device as it manipulates the spinal fixation element from the first orientation to the second.

A person skilled in the art will appreciate that the percutaneous access device **12** can include any number of sidewall openings or slots having any shape that is sufficient to allow a spinal fixation element to be moved from the first orientation to the second orientation. Other embodiments of percutaneous access devices are described in commonly owned U.S. Patent Application Publication No. US 2005/0131421 A1, entitled "Methods and Devices for Minimally Invasive Spinal Fixation Element Placement" and U.S. Patent Application Publication No. 2005/0131422 A1, entitled "Methods and Devices for Spinal Fixation Element Placement," both of which are incorporated by reference in their entirety herein.

FIGS. **5**-**6**B, illustrate another exemplary embodiment of a percutaneous access device **112** that includes an optional guide member **120** formed within the distal end **112***b* of the lumen **112***c* to facilitate guiding the spinal fixation element from a first orientation to a second orientation. The guide member **120** can have a variety of configurations, but it preferably is effective to guide the spinal fixation element from a first orientation toward the anchor **50** attached to, or positioned adjacent to, the access device **112**, and optionally toward anchor(s) implanted in adjacent vertebrae. In an exemplary embodiment, as shown in FIGS. **5**A-**5**B, the guide member **120** is in the form of a sloped shelf formed within the inner lumen **112***c* of the access device **112** and preferably positioned opposite to a single sidewall slot **114** formed in the access device **112**. In an alternate embodiment, shown in FIGS. **6**A-**6**B the sloped shelf can be externally attached to the proximal end of the access device **112** and enter the lumen from the sidewall opening **14**. The sloped shelf can be adjustable to any position within the sidewall opening depending on where the user wants the spinal fixation element to begin changing its orientation. The sloped shelf **120** can vary in shape and size depending on the type of fixation element being used and/or the geometry of the access device. In use, as the leading end of a spinal fixation element, such as a spinal rod, contacts the shelf **120**, the shelf **120** begins to direct the spinal fixation element into the second orientation, thereby causing the spinal fixation element to extend in a direction that is substantially transverse to the axis L of the device **112**, and that is preferably substantially parallel to the patient's spinal column. The spinal fixation element can then be manipulated to position it in relation to one or more spinal anchors, as will be discussed in more detail below.

Referring back to FIG. **1**, in use, the percutaneous access device **12** can be adapted to attach to a spinal anchor **50**. Accordingly, the distal end **12***b* of the percutaneous access device **12** can include one or more mating elements **18** formed thereon or therein for engaging the anchor **50**. Suitable mating elements include, for example, threads, a twist-lock engagement, a snap-on engagement, or any other technique known in the art, and in an exemplary embodiment the mating elements are formed on opposed inner surfaces of the distal end **12***b* of the access device **12**. A sleeve **100** (partially shown in FIG. **5**B) or other device, preferably having sidewall openings (not shown) that correspond with the sidewall openings **14** formed in the percutaneous access device **12**, can also be placed over the percutaneous access device **12**, and optionally over the implant **50** as well, to prevent disengagement of the access device **12** from the implant **50** during use. Exemplary techniques for mating the percutaneous access device **12** to an anchor are disclosed in commonly owned U.S. Patent Application Publication No. 2005/0131408 A1, entitled "Percutaneous Access Devices and Bone Anchor Assemblies," which is incorporated by reference in its entirety herewith. A person skilled in the art will appreciate that a variety of other techniques can be used to removably mate the percutaneous access device to an anchor.

FIGS. **7**-**8**D illustrate an exemplary instrument **80** for holding a spinal fixation element, such as, for example, a spinal rod, and manipulating the spinal fixation element into position relative to a spinal anchor through a cannula, such a percutaneous access device described above. The exemplary instrument **80** has a generally elongate shaft **82** defining a longitudinal axis L that extends between proximal **82***a* and distal **82***b* ends. The distal end **82***b* is adapted to engage a spinal fixation element. The width w_s of the shaft **82** is sized to fit within the lumen of the cannula through which the spinal fixation element is to be introduced. In embodiments in which a percutaneous access device is employed, for example, the width w_s of the shaft **82** is sized to fit within the sidewall openings and lumen of the percutaneous access device. The length l_s of the shaft **82** can vary depending on the cannula with which it is designed to be used. In embodiments in which a percutaneous access device is employed, for example, the length l_s may vary depending on, for example, the length of the percutaneous access device to be used and the sidewall configurations. In the exemplary embodiment, the shaft **82** may have an inner lumen **91** formed therein to provide access to the spinal fixation element and, in certain exemplary embodiments, such as the illustrated embodiment, to accommodate at least a portion of a spinal fixation element engagement mechanism. As discussed in more detail below, the spinal fixation element engagement mechanism allows the instrument to be connected to a spinal fixation element and permits the spinal fixation element to be released from the instrument when, for example, the spinal fixation element is in a final position relative to a spinal anchor.

In the illustrated exemplary embodiment, the proximal end **82***a* of the shaft **82** connects to a handle **86** having a U-shaped configuration adapted to fit around or cup the proximal end of a cannula, such as, for example, a percutaneous access device. The proximal end **87** of the handle **86** has a through-hole **88** to allow an instrument to be inserted therethrough to access the spinal fixation element engagement mechanism and/or the spinal fixation element through the inner lumen **91**.

In certain exemplary embodiment, the spinal fixation element engagement mechanism of the instrument may rigidly engage the spinal fixation element to maintain the spinal fixation element in a fixed position during the entire procedure. Preferably, the spinal fixation element engagement mechanism, in such exemplary embodiments, orients the longitudinal axis of the instrument shaft **82** perpendicular to the spinal fixation element to facilitate entry into the percutaneous access device. For example, the illustrated instrument includes a spinal fixation element engaging mechanism comprising an elongated pin **84** having a threaded distal end **93** for engaging a spinal fixation element. For example, in the illustrated embodiment, the spinal fixation element is a rod having an internally threaded hole **87** positioned thereon for receiving the threaded distal end **93** of the elongated pin **84**. The proximal end **95** of the elongated pin **84** includes a drive feature **85** that is accessible at the proximal end **82***a* of the shaft **82**. The drive feature **85**, and the pin **84**, is retained in position by a retaining pin **97** that limits axial motion of the drive feature **85** relative to the instrument shaft **82** but permits relative rotation. In the exemplary embodiment, the drive feature **85** is generally spool-shaped and includes a hexagonal or other suitable shaped socket **99** for receiving an instrument, such as a screw driver or the like, for rotating the pin **84**. Such an instrument, for example, a screwdriver, may be positioned through the through hole **88** in the proximal end **87** of the instrument handle **86** to engage the drive feature **85**. In operation, rotation of the pin **84** one direction cause the distal end **93** of the pin **84** advance into to the hole **87** in the exemplary rod **70** and rotation in the opposite direction causes the distal end **93** to retreat from the hole **87**.

One skilled in the art will appreciate that the threaded hole **87** may be provided at any position on the rod **70**. In the illustrated exemplary embodiment, for example, the threaded hole **87** is positioned at an end of the rod **70**. In certain embodiments, such as the illustrated embodiment, the rod **70** may have a bullet-shaped tip **71** to facilitate advancement of rod **70** through tissue. In such embodiments, the threaded hole **87** may be positioned at an end of the rod **70** opposite the tip **71**.

In certain exemplary embodiments, the shaft **82** of the instrument **80** may have an extent, at least the distal end **82***b* of the shaft **82**, in a direction transverse to the longitudinal axis L of the shaft **82**, that is less than or equal to the extent of the spinal fixation element in a direction transverse to the longitudinal axis of the spinal fixation element. For example, in the illustrated embodiment, the width w_s is less that or equal to the diameter of the spinal rod **70**. In the illustrated exemplary embodiment, the shaft **82** has a generally circular cross section such that width w_s is the diameter of the shaft **82**. In other exemplary embodiments, the shaft **82** may have a non-circular cross section, including for example, oblong, elliptical, polygonal, and/or rectilinear. In the case of a non-circular cross section, the width w_s can be measured in a direction transverse to the longitudinal axis L of the shaft **82**.

FIGS. **11**A-**11**C illustrate another exemplary embodiment of instrument **300** for positioning a spinal fixation element through a lumen of a cannula. In the illustrated embodiment, the instrument **300** includes instrument shaft **302** having a distal end **310** that is configured to threadingly engage a spinal fixation element, such as, for example, a spinal rod **70**. The instrument shaft **302** includes a lumen **304** through which an actuation mechanism is positioned. In the illustrated exemplary embodiment, the actuation mechanism is an elongated pin **306** that is rotatable within the lumen **304** and includes a distal end **308** having a first gear **312**A formed thereon. The distal end **310** of the instrument shaft **302** is generally L-shaped and includes a laterally offset housing **314** that extends in a direction transverse to the longitudinal axis of the instrument shaft **302**. The laterally offset housing **314** may include a spinal fixation element engaging mechanism, which in the exemplary embodiment comprises one or more gears **312** for translating the rotational motion of the pin **306** to a threaded shaft **318** that is configured to engage an internally threaded hole **87** in the spinal fixation element. In the illustrated exemplary embodiment, three adjacent gears **312**A, B,C are provided, although any number of gears may be provided depending on the application. In the illustrated exemplary embodiment, the threaded shaft **318** is connected to one of the gears **312**A. In operation, rotation of the shaft **306** causes the first gears **312**A to rotate and, through engagement of the gear teeth of the second and third gears **312**B,C, the rotational movement is translated to threaded shaft **318**.

In another embodiment, the instrument rigidly engages the spinal fixation element by a clamping mechanism. The clamping mechanism at the distal end of the instrument shaft can be a jaw clamp **180** having one arm **181** biased in an open position to allow the fixation element to be inserted. The arm **181** has a projection **182** adapted to mate with a groove **183** on the spinal fixation element to secure it within the clamp. An example of a jaw clamp is shown in FIGS. **9**A-B. The arm is spring loaded in the open position and movable to a closed position by using a screwdriver. The clamping arm can mate with any projection such as a lip or tab or indention such as a groove, channel or detent of the fixation element to hold the element in place during manipulation through the percutaneous access device into final position with the spinal anchors. Instead of a jaw clamp, a collet style clamp can be used where two fingers **181**, **183** of the collet are squeezed together by an outer sleeve to clamp a projection **282** on the spinal fixation element. An example of a collet style clamp **280** is shown in FIGS. **10**A-C.

FIGS. **32**A-**38**D illustrate other exemplary embodiments of an instrument **400** for engaging a spinal fixation element, such as a spinal rod **470**, and manipulating the spinal fixation element through a cannula, such as a percutaneous access device described above. In the illustrated exemplary embodiment, the instrument **400** includes a handle **402** and an instrument shaft **404**. The handle **402** may be configured in a manner analogous to the instrument **80** described above and may be connected to the instrument shaft **404** by one or more fasteners **406**. In the illustrated exemplary embodiment, for example, two threaded bolts **406** connect the handle **402** to the instrument shaft **404**. The bolts are received in threaded holes **408** provided in the instrument shaft **404**. In alternative exemplary embodiments, such as that shown in FIG. **38**D the handle **402** and shaft **404** may be of unitary construction.

The instrument shaft **404** of the exemplary instrument **400** may include a lumen **414** through which an actuation mechanism is positioned. In the illustrated exemplary embodiment, the actuation mechanism is elongated pin **416** positioned in the lumen **414**. The pin **416** is rotatable within the lumen **414** and includes a proximal end **418** that includes external threads **420** for matingly engaging internal threads **424** provided in the lumen **414** at the proximal end **422** of the instrument shaft **404**. Rotation of the elongated pin **416** in a first direction causes the distal end **426** of the elongate pin **416** to advance toward the distal end **428** of the instrument shaft **404**. Rotation of the elongate pin **416** in a second direction, opposite the first direction, causes distal end **426** of the elongate pin **416** to retreat from the distal end **428** of the instrument shaft **404**.

The distal end **428** of the instrument shaft **404** is configured to house a spinal fixation element engaging mechanism and to seat the spinal fixation element, which in the illustrated embodiment is a spinal rod **470**. In the illustrated exemplary embodiment, the distal end **428** of the instrument shaft **404** is oriented at an angle to the longitudinal axis and includes an angled lumen **430** that houses and defines a path of motion for the rod engaging mechanism. In the illustrated exemplary embodiment, the path defined by the angled lumen **430** is generally linear and can be oriented between approximately 40° and approximately 60° to the longitudinal axis of the instrument shaft **404**, although, one skilled in art will appreciate that the other shapes and orientations of the path, including, for example, arcuate, are possible. In the exemplary embodiment illustrated in FIG. **38**A, for example, the path is oriented at 45° to the longitudinal axis of the instrument shaft **404**. In the exemplary embodiment illustrated in FIG. **38**B, for example, the path is oriented at 55° to the longitudinal axis of the instrument shaft **404**. The distal end **428** of the instrument shaft **404**, in the illustrated exemplary embodiment, includes a generally hook shaped rod seat **432** positioned distal to and at the terminus of the angled lumen **430**. The rod engaging mechanism, in the illustrated exemplary embodiment, is a cylindrically shaped component **434** that is seated in and movable within the path defined by the angled lumen **430**. The cylindrical component **434** includes a proximal surface **436** and a distal, rod engaging surface **438**.

In operation, rotation of the elongate pin **416** in the first direction causes the distal end **426** of the elongate pin **416** to engage the proximal end **436** of the cylindrical component **434** and advance the distal, rod engaging surface **438** of the cylindrical component **434** into engagement with the rod, thereby fixing the rod **470** between the rod engaging surface **438** of the cylindrical component **434** and the rod seat **432**, as illustrated in FIG. **38**A. Rotation of the elongate pin **416** in the second direction causes the rod engaging surface **438** to be displaced away from the rod **470**, to facilitate removal of the rod. In certain exemplary embodiments, a spring or other biasing mechanism may be provided to bias the cylindrical component **434**, and/or the elongate pin **416**, in a proximal or distal orientation. In the illustrated embodiment, for example, a spring may be provided to bias the rod engaging surface **438** of the cylindrical component **434** distally into engagement with the rod **470**. Alternately, the elongated pin **416** may be rotatably connected to the cylindrical component **434** so that rotation of the pin **416** retracts the cylindrical component **434** away from the rod.

In certain exemplary embodiments, the spinal fixation element may include one or more features to facilitate connection with the instrument. In the illustrated exemplary embodiment, for example, the exemplary spinal rod **470** includes a generally V-shaped notch **472** at the distal end **474** thereof to facilitate engagement of the cylindrical component **434** with the rod **470**, as illustrated in FIG. **39**. An alternate embodiment of an instrument **400'** illustrated in FIGS. **38**B-**38**D, the spinal rod **470** includes a generally W-shaped notch **492** at the distal end **494** thereof to facilitate engagement with the complementary W-shaped distal end **488** of the cylindrical component **434**.

FIGS. **40**-**43** illustrate another exemplary embodiment of an instrument **500** for engaging a spinal fixation element, such as a spinal rod **570**, and manipulating the spinal fixation element through a cannula, such as a percutaneous access device described above. In the illustrated exemplary embodiment, the instrument **500** includes a handle **502** and an instrument shaft **504**. The handle **502** may be configured in a manner analogous to the instrument **80** described above and may be connected to the instrument shaft **504** by one or more fasteners. In alternative exemplary embodiments, the handle and shaft may be of unitary construction.

The instrument shaft **504** of the exemplary instrument **500** may include a lumen **514** through which an actuation mechanism is positioned. In the illustrated exemplary embodiment, the actuation mechanism is linkage **550** positioned in the lumen **414**. The linkage **550** comprises multiple links **552** positioned within the lumen **514** and a proximal handle **554** connected to a proximal link **552**A. In the illustrated exemplary embodiment, the linkage **550** includes three pivotably connected links—first link **552**A, second link **552**B, and third link **552**C. The links **552** cooperate to move within the lumen **514** to adjust the position of the rod engaging mechanism described below. Pivoting the linkage handle **554** from a first position, illustrated in FIG. **42**A, in which the linkage handle **554** is oriented generally perpendicular to the longitudinal axis of the instrument shaft **504**, to a second position, illustrated in FIG. **42**B, causes the third link **552**C to advance distally. One skilled in the art will appreciate that the number of links provided may be varied depending on, for example, the length of instrument shaft **504**.

The distal end **528** of the instrument shaft **504** is configured to house a spinal fixation element engaging mechanism and to seat the spinal fixation element, which in the illustrated embodiment is a spinal rod **570**. In the illustrated exemplary embodiment, the distal end **528** of the instrument shaft **504** is oriented generally transverse to the longitudinal axis and includes a housing for the rod engaging mechanism. In the illustrated exemplary embodiment, the distal end **528** of the instrument shaft **504** includes a rod seat **532**. The rod engaging mechanism, in the illustrated exemplary embodiment, is a generally block shaped component **534** that is pivotable about a pivot axis defined by a pivot pin **536**. The block shaped component **534** includes a first surface **538** and a second, rod engaging surface **540**.

In operation, pivoting of the linkage handle **554** from the first position to the second position causes the third link **552**C of the linkage **550** to advance distally in the lumen **514** and engage the first surface **538** of the component **534**. As the link **552**C is advanced the distally, the component **534** pivots causing the rod engaging surface **534** of the component **550** to engage the rod, thereby fixing the rod **570** between the rod engaging surface **540** and the rod seat **532**, as illustrated in FIG. **40**. In certain exemplary embodiments, a spring or other biasing mechanism may be provided to bias the component **534**, and/or the linkage **550**, in a particular orientation. In the illustrated embodiment, for example, a spring **560** may be provided to bias the rod engaging surface **538** of the component **534** away from the rod seat **532**.

In an alternate embodiment, it may be desirable for the engagement between the instrument and the spinal fixation element to change the orientation of the spinal fixation element with respect to the instrument shaft during the procedure. This embodiment of the instrument has an articulating engagement that allows for manipulation of the fixation element from an orientation parallel with the instrument shaft to an orientation perpendicular to the shaft during the procedure. An example of an instrument allowing these movements is disclosed U.S. Patent Application Publication No. US2005/0131419 A1, entitled "Pivoting Implant Holder" and U.S. Patent Application Publication No. US2005/0131420 A1, entitled "Pivoting Implant Holder," each of which are incorporated by reference in their entirety herein. Another embodiment of an instrument **800** having an articulating engagement with the spinal fixation element is shown in FIGS. **29-30**. The instrument **800** engages a projection **872** on a spinal fixation element, shown as a spinal rod **870**, by a collet **860** extending by a spring **862** from the distal end of the instrument shaft **803**. A locking sleeve **864** locks the projection **872** of the rod **870** within the collet **860**. Articulation of the rod **870** is provided by two linking arms **866** extending from the shaft **803** to the collet **860**, which allow the rod **870** to rotate or pivot.

For reference purposes, FIG. **1** illustrates an exemplary spinal anchor for use with the methods and devices of the present invention. A person skilled in the art will appreciate that a variety of anchors can be used with the devices and methods of the present invention, including, for example, spinal screws, hooks, bolts, and wires. FIG. **1** illustrates a spinal screw that includes a distal, bone-engaging portion, e.g., a threaded shank **54**, and a proximal, U-shaped, receiver member head **52** that is adapted to seat a spinal fixation element, for example a spinal rod. The threaded shank **54** can be fixedly attached to the receiver head **52** to form a monoaxial screw, or alternatively the shank **54** can be configured as a polyaxial screw, as shown, that is rotatably disposed through an opening formed in the distal end of the receiver head **52** to allow rotation of the shank **54** with respect to the receiver head **52**. A variety of techniques can be used to allow rotation of the head **52** with respect to the shank **54**.

FIGS. **12-17** show a minimally invasive method of implanting a spinal fixation element. While the method is shown and described in connection with the percutaneous access device **12** (FIG. **1**), percutaneous access device **212** (FIG. **3**), and spinal screw **50** disclosed herein, a person skilled in the art will appreciate that the method is not limited to use with such devices, and that a variety of other devices described herein and known in the art can be used. Moreover, while only two access devices **12**, **212** and two anchors **50**, **50'** are shown in FIGS. **12-17**, the method of the present invention can be performed using any number of access devices and anchors. The method can also be performed using only some of the method steps disclosed herein, and/or using other methods known in the art.

An example of a procedure for placing the spinal anchors and percutaneous access devices is disclosed in U.S. Patent Application Publication No. US 2005/0131421 A1, entitled "Methods and Devices for Minimally Invasive Spinal Fixation Element Placement," which is incorporated herein by reference. After the anchors **50**, **50'** are implanted with the percutaneous access devices attached, a spinal fixation element **70** may be delivered to the anchor site as described below.

In accordance with one exemplary method, an instrument for engaging and manipulating a spinal fixation element, such as the instrument **80** described above, may be connected to a spinal fixation element, e.g., a spinal rod **70**, as illustrated in FIG. **12**. The shaft **82** of the instrument **80**, with the spinal rod **70** engaged at the distal end of the shaft **82**, may be positioned through the side wall openings **14***b* of the percutaneous access device **212** attached to a second bone anchor **50'** and through the sidewall opening **14***b* of the percutaneous access device **12** attached to a first bone anchor **50**, as illustrated in FIGS. **13** and **14**. The spinal rod **70** may be introduced into percutaneous access device **12** in a first, lengthwise orientation, such that the spinal rod **70** is oriented substantially parallel to the longitudinal axis L of the access device **12**. Where the spinal fixation element has a curved orientation or it has some other configuration, it is understood that the fixation element is in the "substantially parallel" orientation when it is positioned lengthwise through the percutaneous access device.

The spinal rod **70** may be moved through the lumen of the percutaneous access device **12** toward the distal end **12***b*, by moving the handle **86** of the instrument **80** distally, as shown in FIG. **15**. Referring now to FIGS. **16** and **17**, as the spinal rod **70** approaches the distal end **12***b* of the access device **12**, the orientation of the spinal fixation element **70** can be manipulated to direct it towards the spinal anchor **50'** by rotating the handle **86** of the instrument **80** from a position parallel to the patient's spine to a position parallel to the percutaneous access device **12** such that the handle straddles the proximal end of the percutaneous access device **12**. Rotating the handle causes the spinal fixation element **70** to assume a second orientation that is different from the first orientation, and that is substantially parallel to the patient's spinal column and/or transverse to the first orientation. As the handle is rotated to straddle the percutaneous access device **12**, the shaft **82** of the instrument moves through the proximal sidewall opening **14** of device **212** and exits through the proximal end of the device **212**. The shaft **82** of the instrument **80** maintains contact with percutaneous access device **12** until the spinal fixation element **70** has established contact with the distal sidewall opening of percutaneous access device **212**. The sizing of the shaft **82** of the instrument **80** aids in keeping the sidewall openings **14** of the percutaneous access devices **12**, **212** in alignment while the spinal fixation element **70** is being manipulated into position in relation to the spinal anchors **50**, **50'**.

It is understood that the angle of the fixation element **70** in the second orientation will vary depending on the type of fixation device being implanted, as well as the orientation of the access device **12**, which can vary throughout the surgical procedure since the access device **12** can be positioned at several angles with respect to the patient's spinal column.

During transition of the spinal fixation element **70** from the first orientation to the second orientation, a leading end of the spinal fixation element **70** may be positioned below the fascia layer. Referring to FIGS. **16**-**17**, manipulation of the spinal fixation element **70** is continued until the spinal fixation element **70** is positioned in relation to one or more spinal anchors. Depending on the type of spinal anchor used, the fixation element can be positioned to be directly or indirectly mated to the spinal anchor. As shown in FIG. **17**, the fixation element **70** is fully seated in the receiver heads **52**, **52'** of the adjacent spinal anchors **50**, **50'**.

A person skilled in the art will appreciate that the spinal fixation element **70** does not need to be directly attached to each anchor **50**, **50'**, and that it can be indirectly attached to the anchors **50**, **50'** using, for example, a band clamp, or slotted or offset connectors.

To verify that the spinal fixation element is fully seated in the receiver head of the spinal anchor an instrument **90** can be inserted through the proximal end of the percutaneous access device **12** until it can not be advanced any further, as illustrated in FIGS. **18**-**19**. The proximal end **90***a* of the instrument has a marker **94** to indicate the depth from the proximal end of the percutaneous access device to the top of a spinal fixation element fully seated in a spinal anchor. If the marker **94** is aligned with the proximal end **12***a* of the access device, when the instrument is placed down the lumen of the access device, then the spinal fixation element is in the proper position within the spinal anchor and the closure mechanism can be applied, through the access device. The spinal fixation element **70** can then be disengaged from the instrument **80**, which can be removed from the access device **12**. If the marker is not visible above the proximal end of the access device, the fixation element is in not in the proper position and should be repositioned. In an alternate embodiment of the instrument **90**, a closure mechanism may be attached to the instrument **90** and the marker may be employed to indicate if the spinal fixation element is fully seated and if closure mechanism is properly inserted.

Once the fixation element **70** is secured in relation to the implants **50**, **50'**, the access devices **12**, **212** can be removed from the implants **50**, **50'**, leaving only minimally invasive percutaneous incisions in the patient where each access device **12**, **212** was introduced. This is particularly advantageous in that it reduces the amount of trauma caused to the patient, and it minimizes the damage to muscle surrounding the surgical site.

An alternative embodiment of delivering a spinal fixation element, spinal rod **70** to a first bone anchor **50** and a second bone anchor **50'** is illustrated in FIGS. **20**-**25**. In the illustrated embodiment, a first percutaneous access device **212** (FIG. **3**) and a second percutaneous access device **212'** are connected to a first bone anchor **50** and a second bone anchor **50'**. An instrument **80** is connected to the spinal rod **80** (FIG. **20**) and may be employed to position the spinal rod **70** in the proximal side wall openings **14***b* of the first and a second percutaneous access devices **212**, **212'** (FIGS. **21**-**23**) and to manipulate the spinal rod **70** into proximity to the first bone anchor **50** and the second bone anchor **50'** (FIGS. **24**-**25**).

In another embodiment, the percutaneous access device **112** shown in FIGS. **5**-**6**B can be used to facilitate introduction of a spinal fixation element into a surgical anchor site. As previously stated, access device **112** includes a guide member **120** to direct the spinal fixation element **70** from the first orientation to the second orientation. This is illustrated in FIGS. **26**-**28**. As shown, as the spinal fixation element **70** is moved distally to come into contact with the guide member **120**, the guide member **120** causes the spinal fixation element **70** to rotate and extend toward the opening **114** in the percutaneous access device **112**. As a result, the spinal fixation element **70** is directed into the second orientation, whereby it can be positioned in or adjacent to the receiver heads **52**, **52'** of the adjacent spinal implants **50**, **50'**. The guide member **120** can be adjusted along the longitudinal axis of the access device to position the guide at the desired location to contact the spinal fixation element and begin changing its orientation.

As previously stated, a person skilled in the art will appreciate that the exemplary methods described herein can be performed in any sequence using some or any of the steps. Moreover, the percutaneous access devices, instruments, and methods described can be used in any combination to deliver multiple spinal fixation elements simultaneously or sequentially, and/or to perform a variety of other surgical procedures not illustrated or described herein.

FIGS. **47**A-**48** illustrate an instrument **600** for aiding in the insertion and manipulation of a percutaneous access device, such one of the exemplary percutaneous access devices described above. The instrument **600**, as discussed below, is particularly suited to facilitate the delivery and manipulation of a percutaneous device having one or more sidewall openings, such as the exemplary percutaneous access device illustrated in FIG. **3**. The instrument **600** is in the form of a cylindrically-shaped sleeve having a proximal end **612***a*, a distal end **612***b*, and an inner lumen **612***c* formed therein that extends between proximal and distal ends **612***a*, **612***b*. The length of the instrument **600** may vary depending on, for example, the length of the percutaneous access device. In the illustrated exemplary embodiment, for example, the instrument **600** is approximately equal to or less than the length of the percutaneous access device **212**. The distal end **612***b* of the instrument **600** may have a chamfer **615** to ease insertion. The outer surface of the instrument **600** may have surface features to facilitate gripping of the instrument **600**. For example, in the illustrated exemplary embodiment, the outer surface of the instrument **600** includes a plurality of dimples **618** arranged about the circumference of the instrument **600** proximate the distal end **612***b* and the proximal end **612***a*. The inner surface of the instrument **600**, which defines the lumen **612***c*, may have one or more projections extending inwardly therefrom to engage a sidewall opening in the percutaneous access device and inhibit rotation of the instrument **600** relative to the percutaneous access device. In the illustrated exemplary embodiment, for example, in the inner surface of the instrument includes a pair of projections **620** proximate the distal end **612***b* and a pair of projections **620** at the proximal end **612**. The projections **620** are each sized to fit within a sidewall opening of a percutaneous access device, for example, the sidewall openings **14***b* of the percutaneous access device **212**, as illustrated in FIG. **48**. In the illustrated embodiment, each projection **620** in a pair of projections is positioned diametrically opposite the other projection **620** in the pair. In use, the instrument **600** provides rigidity to the percutaneous access device to aid in insertion of the percutaneous access device and bone anchor assembly. Moreover, the instrument **200** may be employed after insertion to facilitate manipulation of the percutaneous access device. For example, the instrument **600** may be used to provide counter-torque and/or for compression or distraction of the bone anchors. The instrument **600** may be removed prior to insertion of the spinal fixation element.

To facilitate insertion of the spinal fixation element having the proper length, a measuring instrument **700** may be used to determine the length of the spinal fixation element for insertion between two bone anchors. The measuring instrument **700**, in the illustrated exemplary embodiment, may have a first arm **710***a* and second arm **710***b* that are connected proximate the proximate end **712***a* of the measuring instrument **700**. In the illustrated exemplary embodiment, the two arms **710***a*, **710***b* pivot around a pivot point **730** relative to one another. The first arm **710***a* and the second arm **710***b* may be connected by a spring **720** that biases the arms **710** away from each other. In the illustrated embodiment, each arm **710** may have a generally cylindrical shape and may tapers along the length from a first diameter at the proximal end **712***a* to a second, reduced diameter at the distal end **712***b*. In the illustrated exemplary embodiment, the diameter of each arm **710** may be less than the inner diameter of a percutaneous access device to permit the arm **710** to be inserted through the percutaneous access device, distally, into proximity with a bone anchor connected to the percutaneous access device and engaged to a vertebra. The distal end **712***b* of each arm **710** may have a spherical tip **715** having a size analogous to a size of a spinal fixation element to facilitate placement of the spherical tip **715** into a bone anchor, for example into the receiver head of the bone anchor. A centering ball **750** may be located along each arm **710** near the distal end **712***b* to center the arm **710** within the percutaneous access device and facilitate proper measurement of the distance between distal ends of the arms **710***a,b*, and thus, the distance between the bone anchors. The measuring instrument may include a locking system **760** to fix the position of the first arm **710***a* relative to the second arm **710***b* and, thus, permit the distance between the distal ends of the arms **710***a, b* to be fixed during a measurement. In the illustrated exemplary embodiment, the locking system **760** may include a threaded rod **767** that intersects the first arm **710***a* and the second arm **710***b* and an internally threaded knob **765** that engages the external threads on the rod **767** and is adjustable along the length of the rod **767**. The knob **765** may be advanced along the rod **767** into contact with the second arm **710***b* to fix the position of the second arm **710***b* relative to the first arm **710***a*. In an alternative embodiment illustrated in FIG. **44**B, a measuring instrument **700'** may have a locking system **760** that includes a slip friction clutch **785** to inhibit over tightening of the knob **765** against the second arm **710***b*.

In operation, the first arm **710***a* of the measuring instrument **700** may be inserted through a first percutaneous access device **212** into proximity to a first bone anchor **50** connected to the first percutaneous access **212** and a first vertebra. The second arm **710***b* of the measuring instrument **700** may be inserted through a second percutaneous access device **12** into proximity to a second bone anchor **50** connected to the second percutaneous access **212** and a second vertebra. In the illustrated exemplary embodiment, the spherical tip **715** of each arm is advanced into contact with the receiver head of the bone anchor. The arms **710***a* and **710***b* may be fixed relative to one another using, for example, the locking system **760**. The arms **710***a* and **710***b* may be removed from the percutaneous access devices **212**, **12** to determine the distance between the distal ends **712***b* of the arms **710***a*, **710***b*. For example, a template block **800** may be employed to facilitate measurement of the distance between the distal ends **712***b* of the arms **710***a*, **710***b*, as illustrated in FIG. **46**. The exemplary template block **800** may include a plurality of openings, markings, or other reference points that are spaced apart a predetermined distance. For example, the template block **800** may include a first opening **810** for receiving the distal end of one of the arms **710** and a plurality of additional openings **820** that spaced apart predetermined distances from the first opening **810**. The template block **800** may include indicia **830** proximate the plurality of second openings that is indicative of the distance between the first opening **810** and one or more of the second openings **820**. A fixation element may be selected based upon the distance measured between the distal ends **712***b* of the arms **710***a*, **710***b*.

In alternative exemplary embodiments, the measuring instrument **700** may include a scale or other device mounted to the instrument to facilitate measuring the distance between the distal ends **712***b* of the arms **710***a*, **710***b* without necessitating removal of the arms **710** from the percutaneous access devices or without necessitating a locking system to facilitate fixing the position of the arms relative to one another.

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A method for introducing a spinal fixation element into a patient's spinal column, comprising:

providing a first percutaneous access devices, the first percutaneous access device having

a proximal end positioned outside a patient's body,

a distal end adapted to couple to a spinal anchor,

a lumen extending between the proximal and distal ends of the first percutaneous access device and defining a longitudinal axis, and

first and second opposed sidewall openings extending from the distal end through at least a portion of the first percutaneous access device, the first and second opposed sidewall openings communicating with the lumen;

providing a second percutaneous access devices, the second percutaneous access device having a proximal end positioned outside a patient's body, a distal end adapted to couple to a spinal anchor, a lumen extending between the proximal and distal ends of the second percutaneous access device and defining a longitudinal axis, and

at least one sidewall opening extending from the distal end through at least a portion of the second percutaneous access device and communicating with the lumen;

engaging a spinal fixation element to a shaft of a manipulator instrument;

wherein the first percutaneous access device has a sleeve disposed therearound and effective to prevent removal of the first percutaneous device from the spinal anchor coupled thereto, the sleeve including at least one sidewall opening formed therein that is adapted to align with the first sidewall opening in the first percutaneous access device;

positioning the shaft of the manipulator instrument through the first and second sidewall opening of the first percutaneous access device, through the at least one sidewall opening of the sleeve, and through the at least one sidewall opening of the second percutaneous access device with the spinal fixation element extends in an orientation substantially parallel to the longitudinal axis of each percutaneous access device; and

rotating the manipulator instrument to change the orientation of the spinal fixation element to a substantially transverse orientation to seat the spinal fixation element in the two spinal anchors, the spinal fixation element rotating through the first sidewall opening of the first percutaneous access device into the lumen of the first percutaneous access device during rotation of the manipulator instrument.

2. The method of claim **1**, wherein the second percutaneous access device includes first and second opposed sidewall openings.

3. The method of claim **2**, wherein one of the percutaneous access devices includes a third and fourth opposed sidewall openings.

4. The method of claim **2**, wherein both of the percutaneous access devices include a third and fourth opposed sidewall openings.

5. The method of claim **1**, wherein the first sidewall opening extends from the distal end and terminates at a position distal to the proximal end.

6. The method of claim **1**, wherein each percutaneous access device is threadably coupled to a receiver head of each spinal anchor.

7. The method of claim **1** wherein each percutaneous access device and spinal anchor are mated together by a twist-lock closure mechanism.

8. The method of claim **1**, wherein the first percutaneous access device is coupled to a receiver head of a spinal anchor, and the first sidewall opening in the first percutaneous access device is adapted to align with a seating portion formed in each receiver head.

9. The method of claim **1**, further comprising delivering a closure mechanism through each percutaneous access device and applying the closure mechanism to each spinal anchor to lock the spinal fixation element to the anchors.

10. The method of claim **1**, further comprising compressing or distracting the bone anchors by manipulating the percutaneous access devices.

11. The method of claim **1**, further comprising implanting the first percutaneous access device through a first minimally invasive incision and implanting the second percutaneous access device through a second minimally invasive incision.

12. The method of claim **1**, further comprising

connecting a first bone anchor to the first percutaneous access device;

implanting the first percutaneous access device and the first bone anchor through a first minimally invasive incision;

anchoring the first bone anchor in a first vertebra;

connecting a second bone anchor to the second percutaneous access device;

implanting the second percutaneous access device and the second bone anchor through a second minimally invasive incision;

anchoring the second bone anchor in a second vertebra, wherein the manipulator instrument seats the spinal fixation element in the first and second bone anchors.

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